FACULTY OF ENGINEERING AND ARCHITECTURE

Designing b.stim: A TES-headset with a focus on usability and personalization

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Preface

It is with pride that I present this Master's Thesis in Industrial Design, the result of a challenging and enriching academic journey. This work represents not only the final milestone of my studies, but also a unique opportunity to contribute to an innovative medical technology with real potential to impact lives.

I would like to express my sincere gratitude to Laís for the opportunity to work on the B.Stim project. Her trust in me to take on her startup as the focus of my thesis was both an honor and a responsibility that shaped the entire course of the project. Her support and insightful feedback, particularly regarding the medical and research-related aspects, were invaluable throughout this process.

My thanks also go to Bastiaan Baccarne and Wouter Devriese, whose guidance and critical insights helped steer the project in the right direction. Their expertise and encouragement provided clarity and confidence at key moments during the development process.

I would also like to thank all the experts and patients who took the time to participate in interviews. Their input grounded the project in real-world needs and ensured that the final design remained closely aligned with user expectations and clinical relevance.

This thesis would not have been possible without the contributions of each of these individuals, to whom I extend my heartfelt thanks.

Abstract

This master's thesis presents the development of B.Stim, a user-friendly and customizable transcranial electrical stimulation (TES) device designed for home use in the treatment of treatment-resistant depression (TRD). Conventional treatments such as antidepressants and clinic-based therapy are often insufficiently effective, difficult to access, or financially burdensome. TES has emerged as a promising, non-invasive alternative that modulates brain activity safely, but most existing devices are either too complex or fail to meet individual user needs.

This project resulted in the design of a modular, intuitive, and adaptable headset. Through iterative prototyping and user research, a solution was developed that follows medical guidelines while allowing a high degree of user autonomy. The electrodes can be freely positioned, the physical design is ergonomic, and the user interface guides individuals step-by-step through the treatment process. The design process combined the Triple Diamond and Biodesign methodologies to integrate needs from both the medical and user contexts.

The functionality and usability of the final concept were validated through user testing with laypersons. B.Stim demonstrates the potential of translating complex medical technologies into accessible home-based solutions, with the broader goal of improving access to mental health care.

Abstract Dutch

In deze masterproef werd B.Stim ontwikkeld: een gebruiksvriendelijk en personaliseerbaar apparaat voor transcraniële elektrische stimulatie (TES), bedoeld voor thuisgebruik bij de behandeling van therapieresistente depressie (TRD). Traditionele behandelmethoden zoals antidepressiva en therapie in klinische setting zijn vaak onvoldoende effectief, moeilijk toegankelijk of financieel belastend. TES vormt een veelbelovend alternatief door op een veilige en niet-invasieve manier hersenactiviteit te beïnvloeden, maar bestaande apparaten zijn vaak te complex of te weinig afgestemd op individuele gebruikersnoden.

Binnen dit project werd een headset ontworpen die modulair, intuïtief en aanpasbaar is. Via iteratief prototypen en gebruikersonderzoek werd een oplossing ontwikkeld die zowel medische richtlijnen volgt als een hoge mate van autonomie toelaat voor de gebruiker. De elektroden zijn vrij positioneerbaar, het ontwerp is ergonomisch, en de gebruikersinterface begeleidt de gebruiker stap voor stap door het behandelingsproces. De ontwerpaanpak combineerde de Triple Diamond en Biodesign methodologieën om noden vanuit zowel medische als gebruikerscontexten te integreren.

De werking en bruikbaarheid van het ontwerp werden gevalideerd via gebruikstesten met leken. B.Stim toont zo aan dat het mogelijk is om complexe medische technologie toegankelijk te maken voor thuisgebruik, met als doel de geestelijke gezondheidszorg te verbeteren.

Designing B.Stim: A TES-Headset with a Focus on Usability and Personalization

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Supervisor: Prof. dr. Bastiaan Baccarne
Counsellors: Laís Boralli Razza, Prof. dr. Wouter Devriese

Abstract **- In recent years, there has been growing interest in accessible and patient-driven mental health solutions, particularly for those suffering from treatment-resistant depression (TRD). This shift has highlighted the limitations of traditional antidepressants and clinic-based therapies, which are often ineffective, costly, or difficult to access[1][2]. Transcranial Electrical Stimulation (TES) has emerged as a promising alternative, offering safe, non-invasive brain stimulation with the potential for at-home use[3]. However, most existing TES devices either lack personalization options or are too complex for independent use[4]. This thesis introduces B.Stim, a TES device designed specifically to overcome these limitations by placing usability and personalization at the core of its development. By integrating the Triple Diamond and Biodesign methodologies[5][6], the design process combined rigorous clinical need-finding with iterative user-centered prototyping. The result is a modular, ergonomic headset that allows users to adjust electrode placement and stimulation protocols in accordance with medical guidance while maintaining a safe and intuitive user experience. Prototyping and validation through user testing demonstrated that B.Stim can be confidently and effectively operated by laypersons in a home setting[7]. The final design supports the broader vision of democratizing access to mental health treatment, offering a practical, personalized, and user-friendly solution for chronic depression management at home.**

Keywords **- Transcranial electrical stimulation; depression; treatment-resistant depression; usability; personalization; home-based therapy**

I. Introduction

Depression presents a significant global health challenge, and the subset of patients with treatment-resistant depression (TRD) remain particularly underserved. Antidepressant medications also often cause intolerable side effects (e.g., sexual dysfunction, weight gain [5]) that lead many patients to discontinue treatment. Standard interventions like medications and psychotherapy are ineffective for a large fraction of patients, leading to TRD rates of roughly 30% among those with depression [4]. Such cases necessitate alternative therapies. Somatic neuromodulation treatments (e.g., electroconvulsive therapy, transcranial magnetic stimulation) can be effective for TRD, but their accessibility is limited by the need for clinical administration and associated costs or side effects. Transcranial electrical stimulation (TES) is an emerging neuromodulation approach that, in principle, could be delivered by patients themselves at home. The concept of at-home TES holds promise for bridging the gap between clinical efficacy and practical accessibility in depression treatment. Yet, current TES devices designed for home use often sacrifice personalization (fixed electrode configurations and limited settings) in order to simplify operation, whereas more flexible systems are confined to lab or clinical environments and demand professional oversight. There is a clear need for a TES solution that combines high usability—so that non-experts can safely use it independently—with a high degree of personalization to tailor therapy to individual needs. The B.Stim project directly tackles this dual need by designing a headset intended to deliver TES for depression in a home setting with maximal user-friendliness and adaptability.

II. Methodology

The development of B.Stim followed a structured, iterative design process drawing on both product design and biomedical innovation practices. A hybrid methodology was formulated by integrating the Triple Diamond design model with the Stanford Biodesign framework [6][7]. The Triple Diamond model (an extension of the well-known Double Diamond process) guided the project through 5 distinct phases of discover, define, develop, validation and deliver. Concurrently, the Biodesign approach ensured focus on the clinical context: starting with the identification of unmet needs in TRD treatment, followed by inventive solution development, and leaving considerations of implementation (regulatory approval, manufacturing) beyond the scope of this academic project[7]. In practice, this combined approach meant that firstly the problem space was thoroughly researched and defined before ideating and prototyping solutions. Which meant understanding TRD patient experiences, technical requirements for TES, and stakeholder input. Iterative cycles of prototyping and evaluation (aligned with the Triple Diamond's validation phase) were conducted to refine usability. This methodology kept both user-centric design principles and medical needs at the forefront throughout the project.

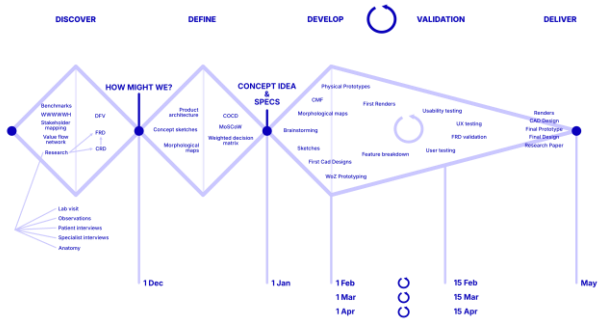

Figure II-1 Methodology

III. Discover

A. Medical and Technical Context

To understand the therapeutic framework for B.Stim, a comprehensive literature review was conducted on depression and the clinical potential of transcranial electrical stimulation (TES). Studies confirmed TES as a safe, non-invasive, and affordable alternative for treating depression, particularly in cases of treatment-resistant depression (TRD). The growing acceptance of home-based TES therapy was also explored to validate the viability of a user-operated device.

B. Regulatory Landscape

To ensure compliance with medical standards, the project analyzed the European MDR 2017/745 regulation, classifying B.Stim as a Class III medical device. This classification influenced design constraints regarding safety, documentation, and CE certification. Preliminary considerations for clinical validation and risk analysis were also established, forming a regulatory baseline for future development.

C. Benchmarking of Existing Solutions

A benchmarking study compared existing TES devices, both clinical and consumer-oriented. The analysis revealed that many consumer devices lacked flexibility in electrode placement and were not tailored for individual montages. Clinical-grade systems, while flexible, often required professional operation. This gap highlighted the opportunity for a user-friendly, yet highly customizable, home-use TES solution.

Competitors	Freedom in electrode placement	Amount of electrodes	Treatment duration	Side-effects	UX	Price
	--	--	+	++	++	€ 459
	--	-	+	++	++	€ 429
	++	++	+	++	--	€ 10 000
Alternatives						
Antidepressants	N/A	N/A	--	--	+	€ 600 - € 1200
Therapy	N/A	N/A	--	+	+	€ 400 - € 1800
TMS	N/A	N/A	+	++	+	€ 3000 - € 9000

Figure III-1 Benchmarking

D. Stakeholder Interviews

In-depth interviews with clinicians, researchers, and potential users enriched the understanding of practical limitations and unmet needs. Clinicians emphasized the importance of safety and correct electrode placement, while users expressed a desire for ease of use and trust in the product. These insights were crucial in framing user requirements and design opportunities.

E. Functional Requirements

The insights from literature, benchmarking, and interviews were translated into a structured Functional Requirements Document (FRD). Key needs included: user-guided electrode placement, intuitive device setup, medical-grade safety, and personalization of therapy protocols. These requirements guided all subsequent design decisions.

IV. Define

A. Opportunity Framing

The insights from the Discover phase were translated into a series of targeted design challenges using the "How Might We" (HMW) method. These questions addressed key opportunity areas such as simplifying the stimulation process, ensuring correct electrode placement, improving comfort, and enabling personalization for different users and therapy protocols. This reframing ensured a solution-oriented mindset at the outset of concept generation.

B. Persona Development

To anchor the design in real user needs, a detailed persona was developed based on patient interviews and user research. This persona represented a middle-aged, tech-wary patient diagnosed with depression, looking for a discreet, non-intrusive, and easy-to-use solution for daily home therapy. The persona helped guide decisions on form factor, interaction, and perceived safety.

C. Ideation and Visual Tools

A range of early concepts were developed through brainstorming and sketching. Tools such as mood boards, CMF (Color, Material, Finish) boards, and morphological maps were used to explore formal, functional, and emotional aspects of the product. This helped define visual direction and identify core mechanical solutions such as the type of headband, electrode system, and interface layout.

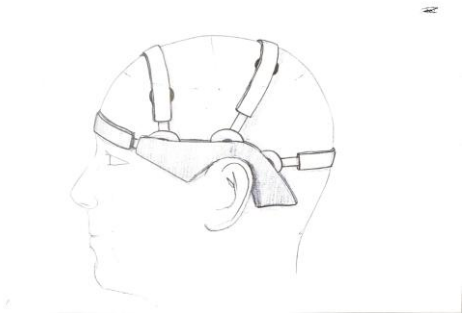

Figure IV-1 Concept sketch

D. Service Design Blueprint

A service blueprint was developed to visualize the full user journey, from device acquisition and onboarding to regular home use and aftercare. This clarified how B.Stim would function not only as a product but as part of a larger service system—especially important for a medical device used in domestic contexts. It also highlighted pain points like storage, reusability of electrodes, and charging logistics.

E. Business Model Exploration

Several delivery models were considered, including direct sales and subscription-based rentals. Given the medical nature

of B.Stim and its potential for shared clinical use, a rental model was selected as the most feasible and sustainable. This approach lowers the financial threshold for users, allows for centralized maintenance, and encourages responsible reuse.

F. Concept Selection

A weighted decision matrix was created to evaluate and rank the proposed concepts based on criteria such as usability, feasibility, comfort, customization, and scalability. This resulted in the selection of three promising directions, each emphasizing a distinct user value:

-Concept A: Maximum personalization and modularity
-Concept B: Maximum comfort and softness
-Concept C: Maximum simplicity and intuitive setup

These three concepts served as the foundation for further development in the next phase.

V. DEVELOP

A. Concept Refinement and Evaluation

Based on the results of the weighted decision matrix in the Define phase, three distinct design directions were refined and further detailed. These represented varied priorities: Concept A emphasized electrode flexibility, Concept B focused on comfort and wearability, and Concept C targeted simplicity and ease of use. Each was visualized through sketching, mock-ups, and ergonomic exploration.

B. Prototyping of Key Elements

To test feasibility and usability early on, low-fidelity prototypes were built using basic materials such as cardboard, split pins and wood sticks. These “quick and dirty” models helped evaluate form factors, headband adjustability, and electrode placement strategies. This rapid prototyping phase provided insights into physical fit, electrode access, and handling intuitiveness from both a user and assembly perspective.

Figure V-1 Low-fidelity prototypes

C. Selection of Final Concept

Following hands-on stakeholder evaluations, a final concept was selected that combined the strengths of previous directions. It retained a soft, comfortable design language, integrated an intuitive sizing mechanism, and included a fully modular electrode system. This system allows for custom electrode placement tailored to therapeutic goals, while ensuring correct and secure mounting through magnetic snap-in connectors and a distributed ring of ports around the band.

D. Mechanical Design for Comfort and Modularity

The final headset design features a dual-band system with a sliding mechanism to accommodate a variety of head sizes. Materials were chosen based on medical-grade standards, with an emphasis on cleanability, skin compatibility, and perceived safety. Surface finishes and color choices were guided by a CMF study to promote calmness and medical trust.

E. Electronics Integration

Parallel to the physical design, an electronic architecture was developed using components such as the OPA2140 for stimulation and TMUX6112 for modular switching. A key addition was a real-time impedance monitoring circuit, integrated to detect poor contact or dry electrodes. This safety system enables the device to automatically halt stimulation when unsafe conditions are detected. All components were selected for compactness, efficiency, and user protection.

F. User Interface Design (UI)

A digital companion application was prototyped in Figma, designed to guide the user through every step of the stimulation process: from preparing the headset and wetting electrodes, to positioning, starting the session, and post-session care. The interface uses plain language, visual cues, and progress tracking.

G. Final Prototype Integration

These elements were merged into a proof of concept prototype. The resulting B.Stim headset successfully embodied the dual objectives of high usability and treatment personalization, while aligning with the constraints of home-based medical care.

Figure V-2 Final prototype

VI. VALIDATION

A. Usability Testing with Laypersons

To assess the real-world feasibility of the B.Stim system, usability tests were conducted with laypersons who had no prior experience with transcranial stimulation devices. Participants were asked to complete a full simulated stimulation session, including all critical steps: wetting the electrodes, placing them correctly, adjusting the headset, launching the app, and running a full treatment cycle.

During these sessions, a think-aloud protocol was applied, allowing insight into user thought processes and friction points. Most users successfully completed the procedure with minimal guidance, demonstrating that B.Stim is accessible to untrained individuals. Users reported feeling reassured by the

magnetic electrode connectors, the modular adjustability, and the calm, structured UI interface.

B. *Quantitative and Qualitative Outcomes*

Task completion rates were high, and setup times decreased with repeated use, indicating a short learning curve. Users consistently highlighted the clarity of the app language and appreciated the error-prevention features (e.g. impedance checks, staged walkthroughs). However, some small usability issues were noted: for instance, unclear instructions on how moist the sponge electrodes needed to be and how to maintain the device post-session.

C. *Iterative Design Adjustments*

Feedback from the usability sessions was directly implemented in a final design iteration. Instructional content in the UI was clarified. This addressed the two most frequent points of confusion. These updates further improved intuitiveness and reduced reliance on external help.

D. *Use-Oriented FMEA*

To anticipate and mitigate possible user-related risks, a use-oriented Failure Modes and Effects Analysis (uFMEA) was conducted on all major system components, including the headset, modular electrodes, and electronics. This analysis covered over 30 potential failure scenarios, ranging from incorrect electrode polarity to physical discomfort.

E. *Validation Outcome*

Overall, validation results confirmed that B.Stim achieves its design goals: it enables safe, independent operation, offers clear, accessible user interaction, and supports clinically relevant personalization of TES therapy. These results strongly support its continued development and future clinical trials.

VII. Deliver

A. *Final Design Documentation*

The B.Stim project was concluded with the creation of a comprehensive design documentation package to support further development. This included:

-Detailed CAD models and technical drawings of all headset components,

-A complete bill of materials (BOM) with sourcing and cost estimation for batch production,

-Basi electronic schematics and layouts for the stimulation and safety systems,

-Preliminary assembly instructions and user guides, laying the groundwork for future production and validation steps.

Figure VII-1 Final design

These outputs aim to facilitate further prototyping, usability refinement, and regulatory preparation, including CE marking procedures under MDR 2017/745.

B. *Societal and Sustainability Reflection*

Sustainability and ethics were considered from early concept stages to final decisions. The rental-based product-service model was selected to make B.Stim more financially accessible to users while allowing centralized maintenance, device reuse, and responsible end-of-life processing. Materials were chosen for cleanability and recyclability where possible, and the design encourages modular replacement of wear parts (e.g. sponge sleeves, electrodes) to extend product life.

C. *Vision for Implementation*

The resulting B.Stim system represents a validated proof-of-concept of a home-use TES headset that balances technical efficacy, clinical needs, and user empowerment. It bridges the gap between clinical therapy and at-home treatment by allowing patients to self-administer personalized therapy safely and with confidence. Through a design process rooted in human needs, the project demonstrates how medical devices can be transformed into accessible, empowering, and user-friendly technologies.

D. *Conclusion of the Project*

B.Stim lays the foundation for future medical device development in the mental health space. While further refinement is necessary this thesis proves that good design can make advanced technologies usable, safe, and appealing to patients. Particularly in mechanical comfort, electronics certification, and clinical trials. With continued development, B.Stim has the potential to become a viable medical product for personalized depression treatment in the home setting.

VIII. Discussion

A. *Reflection*

The design of B.Stim successfully bridges usability and personalization. The modular electrode system enables full flexibility in stimulation configuration, while the headset's intuitive setup and guidance system allow laypersons to operate the device independently. This balance was confirmed during the user testing sessions. However, the comfort of the headset could still be improved to match that of traditional consumer electronics. Additional refinement to the fit and material interface is advised.

B. *Limitations*

The prototype used in testing was 3D-printed and not optimized for manufacturing or long-term comfort. As such, some mechanical tolerances and the overall finish were not representative of a production device. Furthermore, although the electronics designed as a concept, they need to be further developed by a professional in electronic hardware development.

C. *Future Work*

Future development should focus on improving the physical comfort and wearability of the device, particularly in longer sessions. Additionally, the electronics and stimulation circuit require professional development and certification. To bring B.Stim to market, further clinical testing, CE marking preparation, and quality system implementation will be necessary.

D. *Conclusion*

B.Stim demonstrates that transcranial stimulation for depression can be delivered in a usable, safe, and customizable format for home use. The final concept effectively translates clinical requirements into a viable product experience. Although further refinement is needed, this thesis lays the foundation for the successful development of a medical-grade consumer TES device.

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Ontwerpen van B.Stim: Een TES-headset met focus op gebruiksvriendelijkheid en personalisatie

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Counsellors: Laís Boralli Razza, Prof. dr. Wouter Devriese

Abstract **- De voorbije jaren is er een groeiende interesse ontstaan in toegankelijke en patiëntgerichte oplossingen voor mentale gezondheidszorg, in het bijzonder voor mensen die lijden aan therapieresistente depressie (TRD). Deze verschuiving heeft de beperkingen blootgelegd van traditionele antidepressiva en therapieën in klinische settings, die vaak ineffectief, duur of moeilijk toegankelijk zijn[1][2]. Transcraniële elektrische stimulatie (TES) is naar voren gekomen als een veelbelovend alternatief. Het biedt veilige, niet-invasieve hersenstimulatie met potentieel voor gebruik thuis[3]. De meeste bestaande TES-apparaten missen echter personalisatiemogelijkheden of zijn te complex voor zelfstandig gebruik[4]. Deze scriptie introduceert B.Stim, een TES-apparaat dat specifiek ontworpen is om deze beperkingen te overwinnen door gebruiksvriendelijkheid en personalisatie centraal te stellen in de ontwikkeling. Door de Triple Diamond- en Biodesign-methodologieën te combineren[5][6], werd het ontwerpproces opgebouwd rond rigoureuze klinische behoefteanalyse en iteratieve, gebruiksgerichte prototyping. Het resultaat is een modulaire, ergonomische headset waarmee gebruikers de plaatsing van elektroden en stimulatieprotocollen kunnen aanpassen in overeenstemming met medische richtlijnen, terwijl een veilige en intuïtieve gebruikerservaring behouden blijft. Prototyping en validatie via gebruikerstesten toonden aan dat B.Stim op een zelfverzekerde en effectieve manier kan worden bediend door leken in een thuissituatie[7]. Het uiteindelijke ontwerp ondersteunt de bredere visie om toegang tot mentale gezondheidszorg te democratiseren, door een praktische, gepersonaliseerde en gebruiksvriendelijke oplossing te bieden voor de behandeling van chronische depressie thuis.**

Kernwoorden **- Transcraniële elektrische stimulatie; depressie; behandelingsresistente depressie; gebruiksvriendelijkheid; personalisatie; thuisbehandeling**

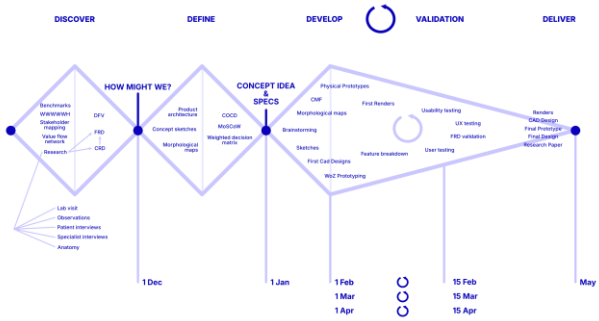
I. Inleiding

Depressie vormt een belangrijke wereldwijde gezondheidsuitdaging, en de groep patiënten met therapieresistente depressie (TRD) blijft in het bijzonder onderbediend. Antidepressiva veroorzaken bovendien vaak ondraaglijke bijwerkingen (zoals seksuele disfunctie, gewichtstoename [5]) waardoor veel patiënten de behandeling stopzetten. Standaardinterventies zoals medicatie en psychotherapie zijn voor een groot deel van de patiënten ineffectief, wat leidt tot TRD-percentages van ongeveer 30% bij mensen met een depressie [4]. In zulke gevallen zijn alternatieve therapieën noodzakelijk. Somatische neuromodulatiebehandelingen (zoals elektroconvulsietherapie en transcraniële magnetische stimulatie) kunnen effectief zijn bij TRD, maar hun toegankelijkheid is beperkt door de nood aan klinische toediening en de bijbehorende kosten of bijwerkingen. Transcraniële elektrische stimulatie (TES) is een opkomende neuromodulatiemethode die, in principe, door patiënten zelf thuis kan worden toegepast. Het concept van TES voor thuisgebruik biedt kansen om de kloof tussen klinische doeltreffendheid en praktische toegankelijkheid in de behandeling van depressie te overbruggen. Toch offeren huidige TES-apparaten voor thuisgebruik vaak personalisatiemogelijkheden op (zoals vaste elektrodeconfiguraties en beperkte instellingen) om de bediening te vereenvoudigen, terwijl meer flexibele systemen beperkt blijven tot laboratorium- of klinische omgevingen en professionele supervisie vereisen. Er is dus een duidelijke nood aan een TES-oplossing die hoge gebruiksvriendelijkheid combineert—zodat niet-experten het apparaat veilig zelfstandig kunnen gebruiken—met een hoge mate van personalisatie om de therapie af te stemmen op individuele behoeften. Het B.Stim-project speelt rechtstreeks in op deze dubbele behoefte door een headset te ontwerpen die TES voor depressiebehandeling mogelijk maakt in een thuissituatie, met maximale gebruiksvriendelijkheid en aanpasbaarheid.

II. Methodologie

De ontwikkeling van B.Stim volgde een gestructureerd, iteratief ontwerpproces dat zowel productdesign als biomedische innovatiemethodes combineerde. Er werd een hybride methodologie opgesteld door het Triple Diamond-ontwerpmodel te integreren met het Stanford Biodesign-framework [6][7]. Het Triple Diamond-model (een uitbreiding van het bekende Double Diamond-proces) leidde het project door vijf afzonderlijke fases: discover, define, develop, validation en deliver. Tegelijkertijd zorgde de Biodesign-aanpak voor een sterke focus op de klinische context: te beginnen met het identificeren van onbeantwoorde noden in de behandeling van TRD, gevolgd door het ontwikkelen van vernieuwende oplossingen, terwijl implementatie-aspecten (zoals regelgevende goedkeuring en productie) buiten het bestek van dit academisch project werden gelaten[7]. In de praktijk betekende deze gecombineerde aanpak dat eerst de probleemruimte grondig werd onderzocht en gedefinieerd, alvorens over te gaan tot het bedenken en prototypen van oplossingen. Dit hield in dat men inzicht verwierf in de ervaringen van TRD-patiënten, de technische vereisten van TES en de input van stakeholders. Iteratieve cycli van prototyping en evaluatie (in lijn met de validatiefase van het Triple Diamond-model) werden uitgevoerd om de gebruiksvriendelijkheid te verfijnen. Deze methodologie hield zowel gebruiksgerichte ontwerpprincipes als medische behoeften centraal gedurende het volledige

project.



Figuur II-1 Methodologie

III. DISCOVER

A. *Medische en technische context*

Om het therapeutisch kader van B.Stim te begrijpen, werd een uitgebreide literatuurstudie uitgevoerd over depressie en het klinisch potentieel van transcraniële elektrische stimulatie (TES). Uit studies bleek dat TES een veilig, niet-invasief en betaalbaar alternatief is voor de behandeling van depressie, in het bijzonder bij therapieresistente depressie (TRD). Ook de toenemende aanvaarding van TES-therapie voor thuisgebruik werd onderzocht om de haalbaarheid van een door de gebruiker bediend apparaat te valideren.

B. *Regelgevend kader*

Om te verzekeren dat aan de medische normen wordt voldaan, werd binnen het project de Europese MDR 2017/745-regelgeving geanalyseerd, waarbij B.Stim werd geclassificeerd als een medisch hulpmiddel van klasse III. Deze classificatie beïnvloedde de ontwerpbeperkingen met betrekking tot veiligheid, documentatie en CE-certificering. Er werden ook voorlopige overwegingen gemaakt voor klinische validatie en risicoanalyse, wat een regelgevend uitgangspunt vormt voor verdere ontwikkeling.

C. *Benchmarking van bestaande oplossingen*

Een benchmarkingstudie vergeleek bestaande TES-apparaten, zowel klinische als consumentgerichte systemen. Uit de analyse bleek dat veel consumentenapparaten onvoldoende flexibiliteit boden in de plaatsing van elektroden en niet afgestemd waren op individuele montages. Klinische systemen daarentegen waren wel flexibel, maar vereisten vaak professionele bediening. Deze kloof benadrukte de opportuniteit voor een gebruiksvriendelijk, maar sterk personaliseerbaar TES-apparaat voor thuisgebruik.

Competitors	Freedom in electrode placement	Amount of electrodes	Treatment duration	Side-effects	UX	Price
	--	--	+	++	++	€ 459
	--	-	+	++	++	€ 429
	++	++	+	++	--	€ 10 000
Alternatives						
Antidepressants	N/A	N/A	--	--	+	€ 600 - € 1200
Therapy	N/A	N/A	--	+	+	€ 400 - € 1800
TMS	N/A	N/A	+	++	+	€ 3000 - € 9000

Figuur III-1 Benchmarking

D. *Stakeholderinterviews*

Diepgaande interviews met clinici, onderzoekers en potentiële gebruikers verrijkten het inzicht in praktische beperkingen en onbeantwoorde noden. Clinici benadrukten het belang van veiligheid en correcte elektrodeplaatsing, terwijl gebruikers vooral eenvoud in gebruik en vertrouwen in het product wensten. Deze inzichten waren cruciaal voor het opstellen van gebruikersvereisten en het identificeren van ontwerpkansen.

E. *Functionele vereisten*

De inzichten uit de literatuurstudie, benchmarking en interviews werden vertaald in een gestructureerd Functioneel Eisen Document (FRD). Belangrijke behoeften omvatten: gebruikergeleide plaatsing van elektroden, intuïtieve installatie van het toestel, veiligheid op medisch niveau, en de mogelijkheid tot personalisatie van therapieprotocollen. Deze vereisten vormden de leidraad voor alle verdere ontwerpbeslissingen.

IV. DEFINE

A. *Kansen definiëren*

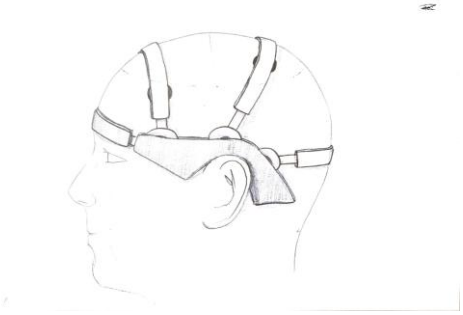
De inzichten uit de Discover-fase werden vertaald naar een reeks gerichte ontwerpopdrachten via de “How Might We” (HMW)-methode. Deze vragen richtten zich op belangrijke opportuniteitsdomeinen zoals het vereenvoudigen van het stimulatieproces, het garanderen van correcte elektrodeplaatsing, het verbeteren van comfort en het mogelijk maken van personalisatie voor verschillende gebruikers en therapieën. Deze herformulering zorgde voor een oplossingsgerichte aanpak bij het starten van de conceptontwikkeling.

B. *Persona-ontwikkeling*

Om het ontwerp te verankeren in reële gebruikersnoden werd een gedetailleerde persona opgesteld op basis van patiëntinterviews en gebruikersonderzoek. Deze persona vertegenwoordigde een middelbare, technologie-onzekere patiënt met een depressiediagnose, op zoek naar een discreet, niet-opdringerig en gebruiksvriendelijk hulpmiddel voor dagelijkse therapie thuis. De persona hielp bij het sturen van beslissingen over vormgeving, interactie en het gevoel van veiligheid.

C. *Ideevorming en visuele hulpmiddelen*

Een reeks vroege concepten werd ontwikkeld via brainstormsessies en schetsen. Hulpmiddelen zoals moodboards, CMF-boards (Color, Material, Finish) en morfologische kaarten werden gebruikt om de formele, functionele en emotionele aspecten van het product te verkennen. Dit hielp om een visuele richting te bepalen en essentiële mechanische oplossingen te identificeren, zoals het type hoofdband, het elektrodesysteem en de lay-out van de interface.



Figuur IV-1 Concept sketch

D. *Service design blueprint*

Een service blueprint werd opgesteld om de volledige gebruikersreis te visualiseren, van de aanschaf van het toestel en de onboarding tot het regelmatig thuisgebruik en de nazorg. Dit maakte duidelijk hoe B.Stim niet enkel functioneert als product, maar ook als onderdeel van een breder dienstverleningssysteem — een belangrijk aspect voor een medisch hulpmiddel dat in een thuissituatie gebruikt wordt. De blueprint bracht ook pijnpunten in kaart, zoals opslag, herbruikbaarheid van elektroden en laadlogistiek.

E. *Verkenning van het businessmodel*

Er werden verschillende leveringsmodellen overwogen, waaronder directe verkoop en abonnementsgebaseerde verhuur. Gezien het medische karakter van B.Stim en het potentieel voor gedeeld klinisch gebruik, werd een verhuurmodel geselecteerd als de meest haalbare en duurzame optie. Deze aanpak verlaagt de financiële drempel voor gebruikers, maakt gecentraliseerd onderhoud mogelijk en stimuleert verantwoord hergebruik.

F. *Selectie van het concept*

Een gewogen beslissingsmatrix werd opgesteld om de voorgestelde concepten te evalueren en te rangschikken op basis van criteria zoals gebruiksvriendelijkheid, haalbaarheid, comfort, personalisatie en schaalbaarheid. Dit leidde tot de selectie van drie veelbelovende richtingen, elk met een eigen gebruikerswaarde:

-Concept A: Maximale personalisatie en modulariteit
-Concept B: Maximale zachtheid en comfort
-Concept C: Maximale eenvoud en intuïtieve bediening

Deze drie concepten vormden de basis voor verdere ontwikkeling in de volgende fase.

V. DEVELOP

A. *Verfijning en evaluatie van concepten*

Op basis van de resultaten van de beslissingsmatrix in de Define-fase werden drie ontwerp-richtingen verder uitgewerkt en verfijnd. Deze richtingen legden elk een andere nadruk: concept A focuste op elektrodeflexibiliteit, concept B op comfort en draagbaarheid, en concept C op eenvoud en gebruiksgemak. Elk concept werd gevisualiseerd via schetsen, mock-ups en ergonomische verkenningen.

B. *Prototyping van kerncomponenten*

Om haalbaarheid en gebruiksvriendelijkheid vroegtijdig te testen, werden low-fidelity prototypes gebouwd met eenvoudige materialen zoals karton, splitpennen en houten stokjes. Deze “quick and dirty” modellen hielpen bij het evalueren van vormgeving, aanpasbaarheid van de hoofdband en strategieën voor elektrodeplaatsing. Deze snelle prototypingfase gaf inzichten in fysieke pasvorm, toegang tot elektroden en de intuïtiviteit van de bediening vanuit zowel gebruikers- als assemblageperspectief.

Figuur V-1 Low-fidelity prototypes

C. *Selectie van het finale concept*

Na praktische evaluaties met stakeholders werd een finaal concept geselecteerd dat de sterktes van de eerdere richtingen combineerde. Het behield een zachte, comfortabele vormentaal, integreerde een intuïtief verstelsysteem voor de maat en bevatte een volledig modulair elektrode-systeem. Dit systeem laat toe om elektroden op maat te positioneren volgens therapeutische doelen, met correcte en veilige bevestiging via magnetische klikconnectoren en een verdeelde ring van aansluitpoorten rond de hoofdband.

D. *Mechanisch ontwerp voor comfort en modulariteit*

Het uiteindelijke ontwerp van de headset bestaat uit een dubbelband-systeem met een schuifmechanisme om verschillende hoofdmaten te accommoderen. De gebruikte materialen werden gekozen op basis van medische normen, met nadruk op reinigbaarheid, huidcompatibiliteit en een veilig aanvoelend oppervlak. Afwerkingen en kleurkeuzes werden bepaald via een CMF-studie (Color, Material, Finish) om rust en medisch vertrouwen uit te stralen.

E. *Integratie van elektronica*

Parallel aan het fysieke ontwerp werd een elektronica-architectuur ontwikkeld met componenten zoals de OPA2140 voor stimulatie en de TMUX6112 voor modulaire schakeling. Een belangrijk onderdeel was de integratie van een real-time impedantiemonitoringcircuit, ontworpen om slechte elektrodecontacten of droge elektroden te detecteren. Dit veiligheidssysteem stelt het toestel in staat om automatisch de stimulatie te stoppen wanneer onveilige omstandigheden worden vastgesteld. Alle componenten werden geselecteerd op basis van compactheid, efficiëntie en gebruikersveiligheid.

F. *Ontwerp van de gebruikersinterface (UI)*

Een digitale begeleidende applicatie werd geprototyped in Figma, bedoeld om de gebruiker door elke stap van het stimulatieproces te leiden: van het voorbereiden van de headset en het bevochtigen van de elektroden, tot het positioneren, starten van de sessie en de nazorg. De interface maakt gebruik van eenvoudige taal, visuele aanwijzingen en voortgangsindicatoren.

G. *Integratie van het eindprototype*

Deze elementen werden samengebracht in een proof of concept prototype. De resulterende B.Stim-headset belichaamt met succes de twee centrale doelen: hoge gebruiksvriendelijkheid en personalisatie van de therapie, terwijl ze blijft voldoen aan de vereisten van medische thuiszorg.

Figuur V-2 Final prototype

VI. VALIDATIE

A. *Gebruikstest met leken*

Om de haalbaarheid van het B.Stim-systeem in realistische omstandigheden te beoordelen, werden gebruikerstesten uitgevoerd met leken zonder eerdere ervaring met transcraniële stimulatie-apparaten. De deelnemers werd gevraagd om een volledige gesimuleerde stimulatiesessie te doorlopen, inclusief alle cruciale stappen: het bevochtigen van de elektroden, deze correct plaatsen, de headset afstellen, de app opstarten en een volledige behandelingscyclus uitvoeren.

Tijdens deze sessies werd een “think-aloud”-protocol toegepast, waarmee inzicht werd verkregen in het denkproces van de gebruiker en mogelijke knelpunten. De meeste gebruikers voltooiden de procedure met minimale begeleiding, wat aantoont dat B.Stim toegankelijk is voor niet-getrainde personen. Gebruikers gaven aan zich gerustgesteld te voelen door de magnetische elektrodeconnectoren, de modulaire verstelbaarheid en de rustige, gestructureerde UI-interface.

B. *Kwantitatieve en kwalitatieve resultaten*

De voltooiingsgraad van taken was hoog, en de installatietijd daalde bij herhaald gebruik, wat wijst op een korte leercurve. Gebruikers benadrukten herhaaldelijk de duidelijkheid van de taal in de app en waardeerden de foutvoorkomende functies (zoals impedantiecontroles en stapsgewijze begeleiding). Er werden echter enkele kleine gebruiksproblemen vastgesteld: bijvoorbeeld onduidelijke instructies over hoe vochtig de spons-elektroden moesten zijn en hoe het apparaat na een sessie onderhouden moest worden.

C. *Iteratieve ontwerpaanpassingen*

Feedback uit de gebruikerstesten werd rechtstreeks verwerkt in een laatste ontwerpiteratie. De instructieve inhoud in de gebruikersinterface werd verduidelijkt, waarbij de twee meest voorkomende verwarringselementen werden aangepakt. Deze updates verbeterden de intuïtiviteit en verminderden de nood aan externe hulp.

D. *Use-Oriented FMEA*

Om mogelijke gebruikersgerelateerde risico’s te voorspellen en te beperken, werd een gebruiksgerichte Failure Modes and Effects Analysis (uFMEA) uitgevoerd op alle belangrijke systeemcomponenten, waaronder de headset, de modulaire elektroden en de elektronica. Deze analyse behandelde meer dan 30 potentiële faalscenario’s, variërend van foutieve elektrodepolarisatie tot fysiek ongemak.

E. *Resultaat van de validatie*

In het algemeen bevestigden de validatieresultaten dat B.Stim zijn ontwerpmissie vervult: het apparaat maakt veilige, zelfstandige bediening mogelijk, biedt duidelijke en toegankelijke gebruikersinteractie, en ondersteunt klinisch relevante personalisatie van TES-therapie. Deze bevindingen ondersteunen sterk de verdere ontwikkeling en toekomstige klinische proeven.

VII. DELIVER

A. *A. Documentatie van het finale ontwerp*

Het B.Stim-project werd afgerond met het opstellen van een uitgebreid documentatiepakket ter ondersteuning van verdere ontwikkeling. Dit omvatte:

-Gedetailleerde CAD-modellen en technische tekeningen van alle onderdelen van de headset.

-Een volledige stuklijst (BOM) met leveranciersinformatie en kostenramingen voor batchproductie.

-Basis elektronische schema’s en lay-outs voor het stimulatie- en veiligheidssysteem.

-Voorlopige assemblage-instructies en gebruikershandleidingen, die de basis vormen voor toekomstige productie- en validatiestappen.

Figuur VII-1 Final design

Deze outputs zijn bedoeld om verdere prototyping, verfijning van de gebruikservaring en voorbereiding op

regelgeving te ondersteunen, inclusief CE-markering volgens MDR 2017/745.

B. Maatschappelijke en duurzaamheidsreflectie

Duurzaamheid en ethiek werden in overweging genomen vanaf de vroege conceptfase tot de uiteindelijke beslissingen. Het verhuur-gebaseerde product-dienstmodel werd gekozen om B.Stim financieel toegankelijker te maken voor gebruikers, terwijl het ook gecentraliseerd onderhoud, hergebruik van toestellen en verantwoord end-of-life beheer mogelijk maakt. Materialen werden geselecteerd op basis van reinigbaarheid en recycleerbaarheid waar mogelijk, en het ontwerp stimuleert modulaire vervanging van slijtgevoelige onderdelen (zoals sponshoezen en elektroden) om de levensduur van het product te verlengen.

C. Implementatievisie

Het resulterende B.Stim-systeem vormt een gevalideerd proof-of-concept van een TES-headset voor thuisgebruik, die technische doeltreffendheid, klinische noden en gebruikersautonomie in evenwicht brengt. Het overbrugt de kloof tussen klinische therapie en thuisbehandeling door patiënten in staat te stellen gepersonaliseerde therapie veilig en met vertrouwen zelfstandig toe te dienen. Door een ontwerpproces dat vertrekt vanuit menselijke behoeften, toont het project aan hoe medische apparaten kunnen worden omgevormd tot toegankelijke, versterkende en gebruiksvriendelijke technologieën.

D. Slot van het project

B.Stim legt de basis voor toekomstige ontwikkeling van medische hulpmiddelen binnen de geestelijke gezondheidszorg. Hoewel verdere verfijning nodig is, bewijst deze thesis dat goed design geavanceerde technologieën bruikbaar, veilig en aantrekkelijk kan maken voor patiënten — met name op het vlak van mechanisch comfort, elektronische certificering en klinische proeven. Met verdere ontwikkeling heeft B.Stim het potentieel om uit te groeien tot een volwaardig medisch product voor gepersonaliseerde depressiebehandeling in de thuissituatie.

VIII. BESPREKING

A. Reflectie

Het ontwerp van B.Stim slaagt erin om gebruiksvriendelijkheid en personalisatie succesvol met elkaar te verbinden. Het modulaire elektrodesysteem maakt volledige flexibiliteit in stimulatieconfiguratie mogelijk, terwijl de intuïtieve opstelling en begeleidingssystemen van de headset leken in staat stellen het toestel zelfstandig te bedienen. Deze balans werd bevestigd tijdens de gebruikerstests. Toch kan het comfort van de headset verder verbeterd worden om te voldoen aan het niveau van traditionele consumentenelektronica. Extra verfijning van de pasvorm en het materiaalcontactvlak is aan te raden.

B. Beperkingen

Het prototype dat in de tests werd gebruikt was 3D-geprint en niet geoptimaliseerd voor productie of langdurig comfort. Daardoor waren sommige mechanische toleranties en de afwerking niet representatief voor een productieklare versie. Bovendien, hoewel de elektronica conceptueel werd ontworpen, moet deze verder worden ontwikkeld door een professional in elektronische hardwareontwikkeling.

C. Toekomst

Verdere ontwikkeling zou zich moeten richten op het verbeteren van het fysieke comfort en de draagbaarheid van het apparaat, vooral bij langdurige sessies. Daarnaast moeten de elektronica en het stimulatiecircuit professioneel worden ontwikkeld en gecertificeerd. Om B.Stim op de markt te brengen, zullen bijkomende klinische testen, CE-markeringvoorbereidingen en implementatie van een kwaliteitsmanagementsysteem noodzakelijk zijn.

D. Conclusie

B.Stim toont aan dat transcraniële stimulatie voor depressie kan worden aangeboden in een bruikbaar, veilig en aanpasbaar formaat voor thuisgebruik. Het finale concept vertaalt klinische vereisten op doeltreffende wijze naar een haalbare productervaring. Hoewel verdere verfijning vereist is, legt deze thesis het fundament voor de succesvolle ontwikkeling van een medisch TES-consumentenapparaat.

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1 Introduction

1.1. Depression and treatment challenges

Depression is one of the most prevalent and debilitating mental health conditions worldwide, affecting an estimated 280 million people and ranking among the leading causes of global disability [1][1]. While first-line treatments such as antidepressant medications and psychotherapy help many patients, a substantial proportion do not achieve full remission. In fact, current treatment methods "fall far short of the ideal," with roughly 20–40% of patients failing to respond adequately to repeated antidepressant trials[2]. Even in large studies of first-line treatment, using distinct antidepressant medications, remission rates were low (only 28% of patients achieved remission on an initial SSRI in the STAR*D trial)[2]. Patients who do not respond to multiple standard treatments are considered to have treatment-resistant depression (TRD), typically defined as major depression that does not remit after at least two adequate antidepressant trials[3]. TRD is not rare, it is often cited to affect roughly one-third of depressed patients, and it is associated with poor clinical outcomes, impaired social functioning, and elevated comorbidities and mortality[4]. These grim statistics underscore the urgent need for more effective and innovative treatment approaches for depression, especially for those patients who do not benefit from existing options.

1.2. Limitations of antidepressants and psychotherapy

Traditional first-line treatments for depression have significant limitations. Antidepressant medications, for example, often come with side effects that compromise patient comfort and adherence, such as sexual dysfunction, weight gain, and sleep disturbances[5]. Such side effects frequently lead to patients discontinuing medication or taking it irregularly, thereby reducing treatment efficacy. Antidepressant can also be difficult to combine with other medication, this can be a problem for the older population and patients with comorbidities. Even when patients do adhere, success is not guaranteed, after two adequate trials of antidepressants, two-thirds of patients still fail to achieve remission[3]. On the other hand, psychotherapy (such as cognitive-behavioral therapy, CBT) requires substantial time and access to trained therapists, and it too has a non-response rate that is far from negligible. This treatment method is also very costly and less scalable, which is a problem in third-world countries. Controlled trials at centers of excellence report CBT response rates around 45–58% over 8–16 weeks, meaning a significant subgroup of patients gain little benefit even with optimal therapy[2]. In summary, while antidepressants and psychotherapy remain the standard of care, their delayed onset of action, side effects, high drop-out rates, and incomplete response rates leave many patients still struggling with depression. This gap in efficacy is particularly pronounced for TRD patients, who by definition have already exhausted these conventional modalities.

1.3. Brain Stimulation Therapies: in the Current Landscape

Given the limitations of medications and talk therapy, a number of brain stimulation treatments have been developed for depression, especially aimed at TRD cases. Brain stimulation refers to a set of techniques that use of electricity to modulate brain activity towards inhibition or facilitation, and can be either non-invasive (e.g., through the scalp), convulsive (e.g., induce seizure) or invasive (e.g., via implanted electrodes), with the goal of studying brain function or treating neurological and psychiatric conditions. The most established brain stimulation invention is electroconvulsive therapy (ECT). ECT is a safe and effective treatment in which small electrical impulses are administered under anesthesia via electrodes placed on the head, inducing a controlled epileptic seizure in the brain. Although the exact mechanism of action is not fully understood, ECT appears to restore the balance of certain neurotransmitters, contributing to a reduction in depressive symptoms. ECT can achieve response in a majority of TRD patients; and remains the gold-

standard treatment for severe or refractory depression due to its high efficacy. However, it has significant drawbacks. It must be performed in hospital under anesthesia and muscle relaxation, and it is associated with several acute side effects (headache, nausea, cardiovascular effects) and notably causes transient cognitive impairment and memory loss as its most common adverse effect [4]. Even though serious complications from ECT are rare, the burden of repeated anesthetized sessions and the risk of cognitive side effects limit its acceptability for many patients.

Transcranial Magnetic Stimulation (TMS) is also an optimal treatment for TRD patients. TMS is a non-invasive brain stimulation therapy which uses magnetic pulses to modulate neural activity. TMS has the advantage of not requiring general anesthesia and has no systemic side effects or cognitive impairments, making it well-tolerated[4]. It has been FDA-approved for adult depression that has failed to respond to at least one antidepressant. However, TMS still requires visiting a clinic for treatment sessions (an electromagnetic coil must be positioned on the scalp by a technician). A typical course involves 20–30 sessions (5 sessions per week for 4–6 weeks) [6], and one of the major obstacles is the considerable time commitment of daily 1-hour visits over many week[4]. This intensive schedule, along with the high cost of repeated sessions (often thousands of dollars in total), can be prohibitive for widespread use despite TMS's favorable side-effect profile.

Another brain stimulation option is Vagus Nerve Stimulation (VNS), a treatment in which a pulse generator implanted in the chest delivers electrical stimulation to the vagus nerve. VNS is FDA-approved as an adjunctive therapy for chronic or recurrent depression that is severe and has not responded to other treatments [4]. In practice, VNS (and the related experimental approach of Deep Brain Stimulation) is reserved for only the most highly resistant cases due to its invasiveness and cost: it requires surgical implantation and carries surgical risks, so it is usually considered only after a patient has even failed ECT. VNS does have a strong safety record from its use in epilepsy and can be effective in some TRD patients; nonetheless, the need for surgery and the high expense mean it is not a broadly applicable solution for the average patient with depression.

In summary, the current treatment landscape for depression ranges from pharmacological and psychotherapeutic approaches to brain stimulation interventions like ECT, TMS, and VNS. Each of these brain stimulation therapies can be life-saving for certain individuals, yet each comes with significant limitations that constrain their use like accessibility, side effects, invasiveness, or cost. This leaves a conspicuous gap in available interventions: patients who have not improved with pills or therapy need alternatives, but the available high-tech interventions are often impractical for routine or widespread use.

1.4. The Need for User-Friendly, Home-Based, and Personalized Solutions

The gap identified above indicates an unmet need for user-friendly, home-use therapeutic devices that could provide safe and effective neuromodulation for depression. Ideally, such a solution would empower patients to continue treatment in their daily home environment, minimizing the burdens of clinic visits or hospitalization. There is growing evidence that this approach is not only desirable but feasible. For example, transcranial direct current stimulation (tDCS), a portable form of low-intensity brain stimulation, has been explored as a home-based treatment. Researchers note that treating MDD with tDCS devices at home "has various logistic advantages compared to tDCS treatment in the clinic."[7]. These advantages include greater convenience, accessibility, and the ability to administer frequent sessions without travel. In fact, a recent multi-site clinical trial of 10-week remotely-supervised home tDCS found it to be safe, well-tolerated, and effective in reducing depressive symptoms compared to sham treatment[8]. This promising result demonstrates the potential of at-home brain stimulation to benefit patients who might otherwise not have access to advanced treatments.

However, early studies of home-administered tDCS also highlight the critical importance of device usability and user guidance. Some trials reported challenges such as skin irritation from electrodes and difficulties with patients following the treatment protocol correctly when unsupervised [7]. These issues underscore that simply having the technology is not enough. The design of the device and the user experience surrounding it are pivotal to ensure safety, efficacy, and adherence in a home setting. In other words, any home-use neuromodulation device for depression must be designed with the end-user in mind, accounting for comfort, simplicity, and personalization to the individual's needs.

1.5. Introducing B.Stim – A TES Headset for Usability and Personalization

B.Stim is proposed as a novel solution to fill this treatment gap: it is a Transcranial Electrical Stimulation (TES) headset designed specifically with usability and personalization as core priorities. TES encompasses technologies like tDCS and related forms of mild brain stimulation delivered via electrodes on the scalp. Unlike large clinical machines or surgically implanted stimulators, B.Stim is envisioned as a lightweight, portable headset that a patient could use at home to administer therapeutic stimulation sessions. By focusing on user-centric design, B.Stim aims to overcome many of the practical barriers seen with current brain stimulation treatments. For instance, the device would incorporate ergonomic electrodes and intuitive controls to make setup and use as simple as possible for a layperson, thereby addressing the issues of correct placement and protocol adherence.

Beyond usability, personalization is a key distinguishing feature of B.stim. Depression is a heterogeneous illness; individuals differ in their symptom profiles, neurobiology, and treatment responses. B.stim is therefore designed to allow tailoring of the therapy to each user. In practice, this could mean adjustable stimulation parameters (such as intensity or montage) that can be optimized for a particular patient's comfort level and therapeutic response, or adaptive algorithms that adjust treatment based on user feedback or symptom tracking. Additionally, the physical design of the headset accounts for anatomical variability, with sizing mechanisms and modular electrode configurations that adapt to different head shapes and sizes. The goal is to move away from a one-size-fits-all mentality and toward a personalized therapy that fits seamlessly into a patient's life. By empowering users with a device that is both easy to use and adaptable to their unique needs B.stim could enhance engagement and sustained use, factors critical for treating a chronic condition like depression.

1.6. The Industrial Design Engineering Perspective

It is no coincidence that the development of B.Stim is being approached from an industrial design engineering standpoint. Complex medical challenges such as TRD benefit from cross-disciplinary innovation, and an industrial design engineer is well-suited to bridge the gap between advanced medical technology and human-centered product design. Whereas clinicians and biomedical engineers ensure that a treatment works medically, industrial design engineers focus on how the treatment is experienced by the user. This background brings expertise in ergonomics, usability, and aesthetics. All of which are crucial for creating a device that patients will actually want to use regularly. In healthcare, poor design can frustrate or even harm users, whereas good design can make technology safer, more effective, and more accessible[9]. An industrial design engineer is trained to apply methodologies of user research, iterative prototyping, and usability testing, which are exactly the processes needed to refine B.Stim into a practical everyday healthcare product. In this project, the designer's perspective ensures that patient experience and needs remain at the forefront, from the overall form factor of the headset down to the interface of the controls. This human-centered approach, coupled with the necessary collaboration with medical experts (neurologists, psychiatrists, and biomedical engineers), creates a synergy where both medical efficacy and user experience drive the design. In summary, the

industrial design engineering background provides the ideal skill set to address the dual challenge at hand: making a depression treatment device that is not only clinically sound but also highly usable, acceptable, and personalized for the people who need it.

To guide the development of this project, the following research question is formulated: “How can a Transcranial Electrical Stimulation (TES) headset for the treatment of depression be designed to maximize usability and personalization in a home-use context?” This question reflects the dual challenge at the heart of the B.Stim project: translating clinical effectiveness into a user-friendly, personalized product experience that fits within the everyday lives of patients with depression. It steers the methodological approach by focusing not only on technical feasibility, but also on how design decisions impact the usability, comfort, and adaptability of the device.

2 Methodology

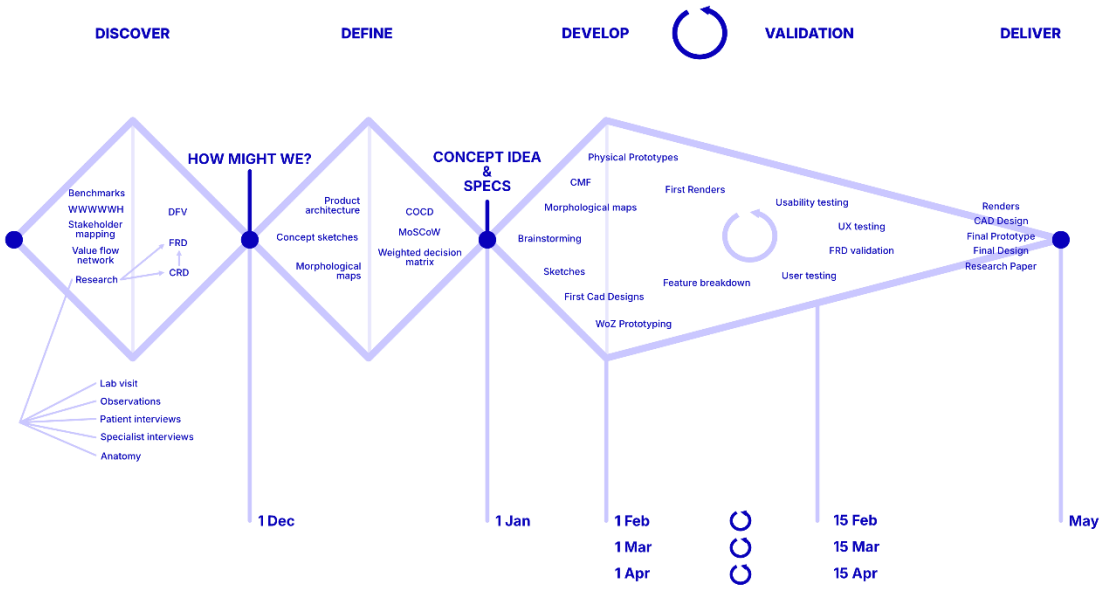

Figure 2-1: Methodology

2.1. Methodology overview

Developing B.Stim required a customized, multidisciplinary methodology that merges principles from both product design and medical device innovation (Figure 2-1). The approach taken in this thesis is an integration of Zendesk’s “Triple Diamond” design model and the Cambridge University (Stanford) Biodesign methodology. The rationale for this hybrid method is to leverage the strengths of each: the Triple Diamond provides a clear, user-centered design process with iterative validation, while biodesign contributes a rigorous focus on clinical needs and viability.

The Double Diamond model from the UK Design Council is a well-known framework organizing design into four phases; discover, define, develop, and deliver. Zendesk’s Triple Diamond is an evolution of this idea, extending it by explicitly adding a third “diamond” for continuous validation before final delivery[10]. In practice, the Triple Diamond framework breaks the innovation journey into distinct segments for discovery, development, validation, and rollout/delivery [11]. This ensures that after devising a solution, the design team loops back to test and refine the concept (the validation phase) before committing to a final product. We embraced this iterative design philosophy in the B.Stim project to

maintain a strong focus on usability: multiple rounds of prototyping and testing were planned so that feedback would continually shape the design.

Complementing this, the biodesign methodology (taught by programs at Stanford and Cambridge) provided a structured approach to the medical and technical aspects of device innovation. The biodesign process is often summarized in three key phases: identify, invent, and implement[12]. First, the identify phase is dedicated to finding and validating an unmet clinical need, through activities like clinical observation, literature research, and stakeholder interviews. Next, the invent phase involves brainstorming solutions and prototyping to address that need, while evaluating factors such as technical feasibility and intellectual property. Finally, the implement phase focuses on the steps required to bring the innovation to market; developing a business plan, navigating regulatory approval, and planning manufacturing and adoption strategies. For the purposes of this thesis, the implement phase was deliberately excluded from our methodology. B.Stim is an early-stage design exploration conducted within an academic context; thus, activities like regulatory clearance, large-scale manufacturing, or commercial go-to-market strategy were beyond the scope of the thesis. By omitting Implement, we concentrated on the front-end stages of innovation; identifying the right problem and inventing an effective, user-friendly solution. These align well with the timeframe and objectives of a master's thesis project.

Integrating the two methodologies: the resulting approach can be thought of as a Biodesign-informed Triple Diamond process. The biodesign's emphasis on deeply understanding the medical problem is preserved (which informed the discover and define phases) and also the careful needs specification before brainstorming solutions. At the same time, the Triple Diamond structure is followed for design and incorporates an explicit validation loop to iterate on prototypes. This integration ensured a multidisciplinary perspective throughout: addressing medical requirements (safety, therapeutic efficacy, clinical workflows) in parallel with user experience requirements (usability, comfort, aesthetics). Notably, Stanford's Biodesign ethos stresses that successful health technology innovation requires multidisciplinary teamwork[12]. For this project this means balancing inputs from clinical experts, engineers, and designers. The hybrid methodology allows to meet that ideal by speaking both the language of clinicians (need statements, risk management, etc.) and of designers (user journeys, ideation, prototyping). The figure above illustrates this custom process, which is divided into five major phases: discover, define, develop, validation, and deliver. Each phase contains specific sub-activities. Importantly, the process is not strictly linear; it is expected to iterate as needed, especially during the development and testing stages. This fluidity aligns with modern design frameworks that acknowledge design "is not a linear process but an iterative one, with continuous refinement and validation throughout the lifecycle."[10]. In the sections below, each phase of the methodology is outlined, the activities involved, and the outputs produced, as well as note how the process evolved during the project.

2.1.1. Discover phase (identifying the problem)

In the discover phase, the goal is to build a comprehensive understanding of the medical, regulatory, and user landscape in which the B.Stim device will be situated. This includes mapping the treatment context of depression and treatment-resistant depression (TRD), as well as exploring the principles, applications, and limitations of Transcranial Electrical Stimulation (TES). To support this, a broad literature review is conducted on TES modalities, depression treatment outcomes, and relevant medical device regulations under MDR 2017/745. Practical insights are gathered through a lab visit at UZ Ghent, where the functioning and handling of TES devices are observed in a clinical setting. In addition, a series of stakeholder interviews is conducted with both patients and mental health professionals to identify firsthand experiences, expectations, and concerns related to neuromodulation technologies. A benchmarking analysis is performed to evaluate the design, functionality, and usability of existing TES and EEG devices. The patient journey is mapped to understand where and how a product like B.Stim could fit into real-life care pathways. Finally, three types of requirement documents; clinical, functional, and design are developed to formalize the needs identified during this research phase.

2.1.2. Define phase (framing the solution space)

The define phase focuses on translating the insights from the Discover phase into actionable design directions. Its goal is to synthesize findings into a clear problem statement, user-centered design strategy, and specification framework. This begins with the formulation of “How Might We” questions that reframe observed problems into design opportunities. A persona is developed to represent a typical user and serve as a touchstone for later design decisions. Several possible business and delivery models for B.Stim are explored, with a focus on sustainable, ethical, and accessible solutions, ultimately favoring a rental-based approach. To visualize the interaction between the user, device, and healthcare system, a detailed service blueprint is constructed. Concept development is initiated through early sketching and visual exploration, supported by AI ideation and moodboarding. These concepts are structured and evaluated using a morphological map and a weighted decision matrix, enabling the objective selection of three promising design directions that will be taken forward into prototyping.

2.1.3. Develop phase (Developing and prototyping the solution)

The develop phase centers on giving form to the selected concept directions through physical and functional development. The main goal of this phase is to create tangible prototypes of the B.Stim headset that can be tested, evaluated, and refined. This begins with the construction of low-fidelity “quick and dirty” prototypes to explore different structural ideas, ergonomic principles, and electrode configurations. These prototypes are used in preliminary evaluations to identify one final concept that offers the best balance between flexibility, usability, and professionalism. This concept is then further developed through refinement of modular features such as the electrode mounting system, sizing mechanisms, and user interface. Materials and surface finishes are explored through a CMF study to ensure the product is comfortable, safe, and trustworthy. A detailed CAD model is created and incrementally revised to accommodate all mechanical and electronic components. The electronics system is also designed during this phase, including component selection, schematic development, and integration of features such as electrode impedance monitoring and LED feedback. In parallel, the user experience is mapped out, and a digital interface is developed in Figma to support guided and safe home use.

2.1.4. Validation phase (testing and iteration)

The validation phase is dedicated to testing the design against the requirements and refining it based on empirical findings. Its goal is to ensure that the device performs as intended in both functional and experiential terms, and that the design meets the needs defined earlier in the process. Usability tests are conducted with representative users to assess comfort, clarity, and ease of use. Observations, think-aloud protocols, and subjective feedback provide insight into design effectiveness and identify areas for improvement. In addition to user testing, functional validation is carried out to ensure the technical elements of the device operate safely and consistently. Clinical feedback is also sought from experts to validate the medical logic and stimulation principles. A use-oriented Failure Mode and Effects Analysis (uFMEA) is conducted to identify potential risks related to safety, comfort, or usability. This structured approach ensures that the device is not only viable in theory, but functionally tested and ready for broader implementation studies.

2.1.5. Deliver phase (final design and documentation)

Finally, the deliver phase focuses on compiling and communicating the final outcomes of the project. The goal here is to consolidate the design into a validated concept and present it through comprehensive documentation. This includes the final B.Stim prototype, a fully detailed CAD model, CMF documentation, and high-quality product renders. All design decisions and refinements are cross-checked against the original requirement documents to verify compliance. The final prototype is evaluated once more to confirm the resolution of prior usability issues. Supporting documents such as technical drawings, interface flows, and functional specifications are made to allow future development or clinical

validation beyond the thesis scope. The project is then formally delivered in the form of this academic thesis, which narrates the full design process, design rationale, and validation results. In doing so, it presents a comprehensive case for B.Stim as a safe, usable, and personalized TES solution for the treatment of depression.

2.1.6. Methodology reflections and evolution

It is worth noting that the methodology itself is a learning process that evolves throughout the course of the thesis. While the project begins with a planned framework it remains responsive to the realities and demands of the design process. For instance, the validation phase becomes more prominent than initially anticipated; early success with rapid prototyping leads to additional rounds of user testing, effectively expanding the scope of this phase. These deviations are not considered setbacks, but rather adaptive strategies that strengthen the project outcome. Modern design approaches encourage this type of flexibility, recognizing that innovation benefits from iteration and continuous learning[10]. The process of designing B.Stim adopts this agile mindset, adjusting timelines and integrating new sub-phases as necessary to respond to challenges and new insights. Ultimately, the combination of Triple Diamond and Biodesign methodologies provides a robust and flexible structure for the B.Stim project. By integrating medical and design requirements from the outset, and by continuously validating the concept with real users, the project navigates the complex space of medical device design in a grounded, user-centered manner. Each phase builds upon the previous one and ensures that the final design of B.Stim is evidence-based, shaped by end-user input, and aligned with the broader goal of improving depression treatment through a usable and personalized device.

3 Discover

3.1. Literature review

The literature review was conducted with the aim of building a foundational understanding of the context in which the B.stim device is being developed, rather than identifying a research gap. Since the design objective was defined at the start of the project, the focus of the review was to gather relevant knowledge to support design decisions and ensure alignment with clinical, technical, and regulatory expectations.

Three main themes were explored:

- Transcranial Electrical Stimulation (TES):
  Literature was reviewed to understand the principles, applications, and efficacy of TES, with a particular focus on its role in the treatment of depression. This provided insight into both the clinical relevance and the technical parameters that must be considered in the design.

- Medical Device Regulation and CE Marking:
  To understand the regulatory pathway for bringing a medical device to the European market, literature was consulted on the Medical Device Regulation (MDR) and the process of obtaining CE marking. This included norms to which the product needs to be conform, risk classification, conformity assessment procedures, documentation requirements, and the role of notified bodies. Based on this understanding, a selection was made of which regulatory steps could realistically be included within the timeline and scope of a thesis project.

- Framing the Depression Problem:

Research was also conducted on the nature of depression, patient experiences, and existing treatment limitations. This builds a human-centered understanding of the user context, helping to make design decisions with an user centered perspective.

This review provided the theoretical, clinical, and regulatory grounding for the subsequent development phases and ensured that design choices were informed, compliant, and aligned with user and stakeholder needs.

3.1.1. TES

Transcranial electrical stimulation (TES) is a non-invasive neuromodulation technique that aims to modulate neural activity through the application of low-intensity electrical currents (usually 1-4mA) to specific brain regions. The technique involves the use of surface electrodes to deliver electrical current across the scalp, typically using a positive electrode (anode) and a negative electrode (cathode)[13]. The direction of the current—entering through the anode and exiting through the cathode—can either increase (anodal stimulation) or decrease (cathodal stimulation) cortical excitability, depending on the polarity and targeted brain region[14].

There are several TES modalities that differ in how the current is applied:

- Transcranial Direct Current Stimulation (tDCS): Delivers a constant, low-level direct current between fixed anode and cathode electrodes.

- Transcranial Alternating Current Stimulation (tACS): Applies an oscillating current that switches polarity at specific frequencies, intended to entrain neural oscillations.

- Transcranial Random Noise Stimulation (tRNS): Uses a randomly fluctuating current in both amplitude and frequency, hypothesized to enhance neural plasticity through stochastic resonance.

- High-Definition TES (HD-TES): Employs an array of smaller electrodes to provide more focal and targeted stimulation compared to traditional sponge electrodes.

TES is typically administered using rubber electrodes encased in saline-soaked sponges, secured to the scalp using an elastic band or cap. Electrode size is usually between 20–35 cm^2, though this may vary depending on the desired current density and stimulation area. Electrode placement is often guided by the International 10–20 EEG system, a standardized method used to locate cortical targets [15] (see Figure 3-1).

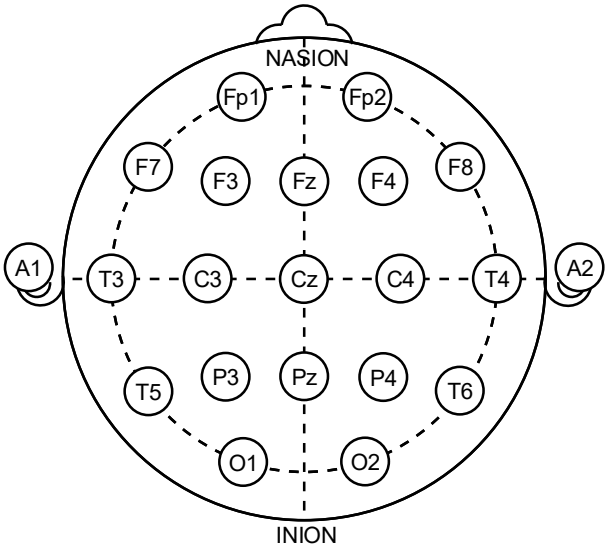

Figure 3-1: 10-20 EEG system

In recent years, TES has gained increasing attention as a potential treatment for various mental health disorders, particularly major depressive disorder (MDD). The technique aims to modulate dysfunctional brain networks by upregulating or downregulating cortical activity, particularly in the dorsolateral prefrontal cortex (DLPFC)—a region often implicated in mood regulation. Current research also explores the feasibility of home-based TES interventions, which could enhance accessibility and adherence in long-term treatment scenarios. [16]

TES is generally considered safe and well-tolerated. No serious adverse effects have been reported in the literature. Moderate adverse events, such as skin burns, are rare and typically attributed to poor electrode-skin contact. Mild side effects, including headache, fatigue, and skin irritation, are more common but occur in both active and sham stimulation conditions. When conducted under appropriate clinical guidelines, including limiting stimulation intensity to below 4 mA and session durations to under 60 minutes, TES is associated with a favorable safety profile.

3.1.2. Depression

According to the World Health Organization[17], depression affects approximately 280 million people worldwide, making it one of the most prevalent mental health conditions globally. It can occur at any age but is particularly common in adolescents and older adults. Women are statistically more likely to experience depression than men. While depression is distinct from temporary emotional responses to life challenges, if left untreated, it can become a serious health condition and lead to severe consequences such as suicide. These figures underline the urgent need for effective, accessible, and sustainable treatment options.

Depression or Major depressive disorder (MDD) is characterized by a persistent loss of pleasure, feelings of hopelessness and sadness, reduced motivation, cognitive impairments, and various somatic symptoms[18]. The most commonly applied treatment modalities include pharmacotherapy, psychotherapy, and somatic interventions[19]. While antidepressant medication can be effective, it often comes with a range of side effects, including nausea, gastrointestinal disturbances (such as diarrhea and constipation), insomnia, agitation, headaches, dizziness, dry mouth (xerostomia), and sexual dysfunction[20][20]. Psychotherapy, although beneficial for many, does not guarantee improvement and may in some cases even lead to deterioration[21][21]. Somatic treatments such as electroconvulsive

therapy (ECT), transcranial magnetic stimulation (TMS), vagal nerve stimulation (VNS), and deep brain stimulation (DBS) offer alternatives but are often invasive, expensive, and associated with their own set of risks[22]. Transcranial electrical stimulation (TES) has emerged as a promising complementary or alternative approach. It offers a non-invasive, low-cost, and accessible treatment option with minimal and generally mild side effects, making it a compelling candidate to bridge the gap in current depression care.

3.1.3. MDR

The European Medical Device Regulation (EU) 2017/745 (MDR)[23], which came into full effect on May 26, 2021, replaced the previous Medical Devices Directive (MDD 93/42/EEC)[24]. This regulation ensures the safety, transparency, and traceability of medical devices across the European market. Key updates include stricter requirements for clinical evaluation, post-market surveillance, and technical documentation.

Transcranial electrical stimulation (TES) devices fall under the scope of medical devices due to their intended neurological effect on the body. According to Annex VIII of the MDR, devices are classified based on risk, duration of use, invasiveness, and the degree of interaction with the human body. A TES device is classified as Class III because of a reclassification document added to the MDR since December 1st 2022[25].

To obtain a CE mark under MDR for a Class III device such as B.stim, the following key steps must be followed[22]:

- Risk Classification
  Confirm the classification based on the device's intended use and inherent risks (already determined as Class III).

- General Safety and Performance Requirements (GSPRs)
  Demonstrate compliance with the essential safety and performance principles outlined in Annex I of the MDR.

- Clinical Evaluation
  Provide clinical evidence that the device performs as intended and does not pose unacceptable risks. This includes clinical investigation data or a thorough analysis of existing data from similar devices.

- Technical Documentation
  Create a complete technical file containing design, risk analysis, manufacturing processes, validation data, labeling, and instructions for use.

- Quality Management System (QMS)
  Implement an ISO 13485-compliant QMS that covers all aspects of the device's lifecycle.

- Notified Body Involvement
  Engage with a designated Notified Body to review the technical documentation and QMS, and to conduct audits and evaluations prior to issuing the CE certificate.

- Post-Market Surveillance (PMS) and PMCF
  Establish a system for monitoring the device after it enters the market, ensuring ongoing safety and performance.

Given the complexity of MDR and the classification of B.stim as a Class III device, not all steps are feasible within the scope of this thesis. Achievable steps that will be included in the design process of the B.Stim for this thesis:

- Mapping and understanding the regulatory pathway.
- Preparing early-stage technical documentation (e.g., intended use, risk analysis, technical drawings, materials).
- Identifying and implementing applicable general safety and performance requirements (GSPRs).
- Well documented design process for later review and use.

Long-term steps, such as clinical investigation, full CE marking, and Notified Body engagement, fall beyond the thesis timeline and would be carried out during subsequent stages of product development in collaboration with the startup and clinical partners.

3.1.4. Conclusion

This literature review provides a strong foundation for understanding the clinical, technical, and regulatory context in which B.Stim is being developed. By examining the principles of transcranial electrical stimulation (TES), the nature of depression, and the framework of the Medical Device Regulation (MDR), the groundwork has been laid for making well-informed design decisions in the next phases of the project. However, while this review offers a solid starting point, further exploration is necessary to gain a deeper understanding of the specific design requirements for B.Stim.

3.2. Lab Visit

To gain hands-on experience with transcranial electrical stimulation (TES), a lab visit is conducted at UZ Ghent under the guidance of Laís Boralli Razza. This visit provides valuable practical insights that extend beyond the scope of literature. It offers the opportunity to observe real-life TES procedures, including electrode placement, session setup, interaction protocols, and the components of a TES device. In addition to these observations, several benchmark devices were available for evaluation, these will be discussed in detail in a subsequent chapter.

During the lab visit, a transcranial direct current stimulation (tDCS) session is observed, following a structured process:

The participant begins by making themselves comfortable and ensuring their head is accessible by removing any headwear. The sponges surrounding the electrodes are hydrated with a saline solution or saline paste to ensure optimal conductivity. These sponges must be fully saturated, but without excessive liquid dripping.

Electrode placement is determined based on the condition being treated. Although research is ongoing to identify the most effective configurations, for major depressive disorder, the electrodes are most commonly placed on the prefrontal cortex—specifically at positions F3 and F4 according to the International 10–20 EEG system[26]. Larger distances between electrodes are generally associated with increased cortical modulation, as the current is drawn more deeply through the brain rather than across the scalp[27].

A medical professional secures the electrodes using elastic rubber bands and connects them to the stimulation device. Once all connections are in place and checked, the stimulation session begins. It typically lasts between 20 and 30 minutes. To ensure a safe and comfortable experience, the current gradually ramps up to the desired intensity at the start of the session and ramps down again at the end.

This session offers valuable insight into the practical execution of a TES procedure. However, it is conducted using a research-grade TES device, which is complex and intended to be operated by trained medical professionals. While informative, it also highlights the importance of exploring devices that are specifically designed with user-friendliness in mind and suited for potential home use. These devices offer different design considerations and are essential to understanding how TES can be made more accessible for everyday users.

3.3. Benchmarks

To better understand how existing TES devices are designed and used, a benchmark analysis is conducted. The goal of this analysis is to identify best practices, usability trends, and design shortcomings in the current landscape, which can provide valuable input for the design of the B.Stim.

The benchmarking focused on comparing various TES devices, especially those designed for home use, as these align closely with the intended direction of the B.Stim. In addition, alternative treatment options for depression, such as antidepressants, psychotherapy, and transcranial magnetic stimulation (TMS), are included to provide a broader context.

3.3.1. Device Categories

Based on usage context and design orientation, the benchmarked TES devices can be categorized into three main groups:

- Lab-Use Devices
  These are research-grade headsets that offer a high degree of flexibility in stimulation settings and electrode configurations. However, they typically lack user-friendly features and require supervision by trained professionals, making them unsuitable for home use.

- Home-Use Devices
  Designed for individual use without medical oversight, these headsets prioritize user experience, safety, and simplicity. These often sacrifice flexibility in stimulation parameters and restrict electrode placement options to maintain safety and ease of use.

- Hybrid Devices
  These attempt to combine the flexibility of lab-grade systems with a more accessible user interface. While promising, they often involve trade-offs in terms of performance, cost, or ease of operation.

3.3.2. Comparison Criteria

To assess the value and relevance of each benchmarked device or treatment, a set of qualitative criteria are used:

- Freedom in Electrode Placement
  The degree to which users can customize where electrodes are placed.

- Number of Electrodes
  The quantity of electrodes that can be used simultaneously, and whether this number is configurable.

- Treatment Duration
  How long a typical treatment takes, including both individual session length and the overall therapy period.

- Side Effects / Adverse Effects
  Frequency and severity of reported side effects, whether physical or psychological.

- User Experience
  The ease of use, comfort, clarity of instructions, and general accessibility of the device or treatment.

- Treatment Cost
  Approximate cost of the treatment, including equipment, medication, or sessions.

Each factor is rated using the following qualitative scale (Figure 3-2):

- - - Very Poor
- - Poor
- + Good
- ++ Very Good

Competitors	Freedom in electrode placement	Amount of electrodes	Treatment duration	Side-effects	UX	Price
	--	--	+	++	++	€ 459
	--	-	+	++	++	€ 429
	++	++	+	++	--	€ 10 000
Alternatives						
Antidepressants	N/A	N/A	--	--	+	€ 600 - € 1200
Therapy	N/A	N/A	--	+	+	€ 400 - € 1800
TMS	N/A	N/A	+	++	+	€ 3000 - € 9000

Figure 3-2: Benchmark comparison

3.3.3. Key Findings

The benchmark reveals a trade-off between functionality and user experience in current TES devices. Devices that offer high flexibility in electrode placement and stimulation often score poorly on usability and accessibility. And on the other side, home-use devices offer intuitive operation and a smooth user experience but tend to limit the user's control over the stimulation parameters.

This presents a clear opportunity for the B.Stim device to position itself uniquely by combining the customizability of research-grade systems with the intuitive and user-friendly experience typical of consumer products.

When compared to alternative treatments, TES offers advantages in terms of safety, duration, and cost. However, treatments like antidepressants and psychotherapy often come with long durations and/or side effects. While TMS scores well across most factors, it remains a costly and clinic-bound solution.

3.3.4. Additional Design Benchmarking

Beyond functional comparison, the benchmark analysis also includes a review of the design and product architecture of a broader selection of TES and EEG headsets. EEG devices are included due to their structural and functional similarities to TES devices, particularly regarding electrode-based interaction with the scalp.

This analysis helped identify:

- Common structural elements (e.g., headband systems, wire routing)
- Electrode attachment mechanisms
- Key pain points in user interaction
- Materials and form factors that support comfort and compliance

These insights will inform material selection, product structure, and assembly strategies for B.Stim. A comparative analysis of TES and EEG headsets reveals several recurring patterns in design and product architecture, both positive and negative, that can inform the development of the B.Stim.

3.3.4.1. Positive Design Trends

- Headphone-Inspired Sizing Mechanisms
  Many headsets adopt a sizing mechanism similar to over-ear headphones, offering adjustability and familiarity for users.

- External Device Control
  Instead of integrating complex controls into the headset, most devices rely on external interfaces. These are typically smartphone applications, to manage settings and sessions. This contributes to a cleaner, more intuitive user experience.

- Comfort-Oriented Contact Points
  Soft padding or flexible materials are often used at the contact points with the head to enhance user comfort, especially during longer sessions.

- Minimal and Sleek Aesthetic
  Devices commonly feature a streamlined, minimalistic design, aligning well with the expectations for modern medical technology.

- Wireless Operation
  Most headsets operate wirelessly, which improves mobility and reduces clutter during use.

- Status Indicators

The inclusion of LED indicators to display device status (e.g., on/off, battery level) is a widely used and effective feature for user feedback.

3.3.4.2. Design Limitations

- Limited Customization in Electrode Placement
  A major shortcoming across many of the benchmarked devices is the lack of flexibility in electrode positioning. This limits the therapeutic potential and personalization of the treatment.

3.3.4.3. Morphological Analysis

To further support the design process, a morphological table was developed. This table catalogs a wide range of functional and structural aspects observed in the benchmarked devices, including:

- Sizing mechanisms
- Scalp contact points
- Battery types
- Water ingress protection levels (IP ratings)
- Wireless connectivity
- Electrode attachment methods

This table serves as a foundational tool for exploring and selecting design options for the B.stim device and is included in Appendix A for reference throughout the design process.

The benchmark analysis provides a comprehensive overview of the current landscape of TES and related neurotechnology devices. By evaluating their functionality, usability, and design architecture, key insights have emerged regarding both opportunities and challenges in the development of B.Stim. Notably, the gap between clinical-grade flexibility and user-friendly design in home-use devices presents a clear opportunity for innovation.

Additionally, the morphological analysis offers a structured foundation for design ideation in the next phase of development. However, understanding the technical and structural landscape alone is not sufficient. To design a product that is truly user-centered and clinically relevant, the perspectives of stakeholders—such as medical professionals, patients, and researchers—must also be integrated.

3.4. Interviews

To gain deeper insight into the practical use, perceived challenges, and user needs surrounding TES devices, a series of interviews are conducted with key stakeholders, including clinicians, researchers, and potential users. These interviews provide qualitative input that complements the findings from the benchmark analysis and help translate general trends into specific, actionable design criteria for the B.Stim device.

All interviews are conducted in accordance with ethical research practices. Prior to participation, interviewees signed an informed consent form, confirming their voluntary involvement and understanding of the research goals. In addition,

a Non-Disclosure Agreement (NDA) is signed to ensure confidentiality and protect any sensitive or proprietary information discussed during the interviews.

An interview protocol is followed to ensure consistency across all sessions. This protocol coveres topics such as device usability, clinical procedures, patient interaction, and expectations for home-use systems.

3.4.1. Expert protocol

Introduction (5 min)

- Brief overview of B.Stim:
  Startup initiative involving Laís Boralli Razza and Expedition DO
- Focus on home-use tDCS for depression
- Prioritizing customizability and user-friendliness

1. Benchmarks and device evaluation (10 min)
   - Have you heard of or worked with devices like Flow, Platowork or Diadeem?
   - What do you see as their strengths and weaknesses?
   - How would you rank them in terms of usability, clinical potential and safety?
   - Are there design or functional gaps you've noticed in these products?
2. Business models (5 min)
   - What's your opinion on different pricing structures for medical devices like B.Stim?
   - Direct purchase
   - Subscription or rental
   - Pay-per-session
   - Which model seems most sustainable and accessible to users?
3. Clinical and safety considerations (10 min)
   - What are the key factors that determine efficacy for brain stimulation devices?
   - What are primary safety concerns for at-home use, and how can they be addressed?
   - How much professional oversight is typically needed?
   - Should there be limits on frequency or cumulative session use?
4. Customizability and expectations (5 min)
   - How important is personalizability in tDCS treatments?
   - If you were a user, what would you hope to get out of the device?
   - What kind of support or guidance should be provided to ensure safe, effective use?
5. Feature evaluation (5 min)
   - Please share your thoughts on the following potential features:
   - Affordable pricing
   - Dry electrodes
   - Freedom in electrode placement
   - Foldability for portability
   - App integration & control
   - Data tracking for treatment sessions

3.4.2. Patient protocol

Introduction (5 min)

- Introduction to B.Stim in simple terms:
  - It's a new type of headset that uses gentle electrical currents to help with depression.
  - Designed for safe use at home, focused on comfort and personalization.
- You're helping us understand how we can make it more usable and helpful.
- Confirm signature of informed consent form and NDA.

1. Experience and expectations (5 min)
   - Have you ever used a mental health or wellness device before (e.g. meditation apps, light therapy)?
   - If you had a device that could help manage depression, what would you want it to do for you?
2. Evaluation of existing devices (5 min)
   - Have you heard of Flow, Platowork, or Diadeem?
   - What do you think about how these look or work (show images if possible)?
   - What would make you more likely to trust or use a device like this?
3. Safety and comfort (5 min)
   - Would you feel safe using a device like this at home?
   - What concerns might you have (setup, electrodes, electrical stimulation)?
   - How important is comfort or flexibility in how you wear it?
4. Preferences and features (10 min)
   - What do you think about these possible features? (Ask for opinions, ranking, or priorities)
     - Affordable pricing
     - Dry electrodes (no gels or liquids needed)
     - Adjustable electrode placement
     - Foldable design
     - Smartphone app control
     - Data tracking or progress visualization
5. Pricing and support (5 min)
   - What kind of support would help you feel confident using this device? (Tutorials, in-app help, live chat?)
   - What would be a fair price for such a device or service?

3.4.3. Key insights from interviews

The interviews reveal several critical considerations for the development and implementation of the B.Stim device:

- Misuse concerns:
  There is significant concern about the potential for incorrect or unsafe use by patients, especially without proper guidance or restrictions.
- Electrode placement accuracy:
  Ensuring accurate and consistent electrode placement is considered crucial for treatment efficacy.
- Positive perception of B.Stim's goals:
  Experts responded favorably to the concept behind B.Stim, particularly its focus on user-friendliness and home-based treatment for depression.
- Professional aesthetics matters:

The visual design of the device should convey professionalism and medical legitimacy to encourage patient trust and compliance.

- Dry electrodes – promising but questioned:
  While dry electrodes are appreciated for their convenience and comfort, there is skepticism about whether they can deliver the same effectiveness as traditional wet electrodes.
- Specialist as a B2B customer:
  The idea of specialists acting as intermediaries—renting out the device to patients—introduces opportunities but also risks, particularly in terms of responsibility and potential malpractice.
- Lack of reimbursement:
  Currently, TES treatments are not reimbursed by health insurance providers, which may pose a barrier to widespread adoption.
- Understanding the patient journey:
  Experts emphasized the importance of mapping out the full patient experience. Typically, an initial treatment phase lasts around three weeks, followed by optional maintenance or follow-up sessions.
- Controlled flexibility:
  While customizability is valued, experts advised limiting patient autonomy in adjusting stimulation settings. Instead, stimulation presets determined by a healthcare professional were recommended to ensure safe and effective treatment.
- Expectations for support:
  Users expressed a strong need for clear guidance and support, especially during initial setup. Step-by-step tutorials or in-app help were preferred, and some also valued the idea of being able to reach out to real people (e.g., through live chat).
- Perceived safety concerns:
  While most users said they would feel safe using the device at home, there were recurring concerns about electrical stimulation near the brain, misuse, and proper electrode placement. Preset settings and clear instructions were seen as essential to counter this.

The insights gathered from these interviews are important in shaping a user-centered development approach for the B.Stim device. Both experts and potential users emphasized the need for clear guidance, controlled flexibility, and a feeling of safety while using the device. Practical challenges are identified such as reimbursement, electrode placement, and risk of misuse. These findings provide a good foundation for translating clinical research into a product that is both safe and accessible for home use.

3.5. Patiënt journey

Understanding the patient journey is crucial for designing an effective and user-centered solution like B.Stim. It provides insight into the real-life experiences of individuals living with depression—how they recognize symptoms, seek help, undergo treatment, and respond to different interventions. This perspective ensures that B.Stim aligns not only with clinical effectiveness but also with patients' needs, expectations, and challenges throughout their care pathway.

By combining insights from literature with interviews conducted with both patients and healthcare professionals, the following comprehensive overview is constructed:

- Recognition of symptoms
  The patient begins to experience and recognize persistent symptoms such as low mood, fatigue, or difficulty concentrating.

- Consultation with a general practitioner (GP)
  The GP conducts an initial screening for depression and may provide a referral to a mental health specialist.
  → Common issues: misdiagnosis, ineffective medication as first-line treatment.

- Evaluation by a psychologist or psychiatrist
  A mental health professional assesses the severity of the depression through structured interviews or diagnostic tools.
  → Psychiatrists typically intervene in moderate to severe cases.
  → Recommendations may include therapy, medication, or lifestyle changes.

- First-Line treatment: therapy and/or medication
  Patients typically start with Cognitive Behavioral Therapy (CBT), other psychotherapy methods, or antidepressants.
  → Multiple medications may be trialed before finding one that works.
  → This stage may last several months to a year, depending on response.

- Reevaluation of treatment response
  If symptoms persist or worsen, alternative treatments are considered, such as Transcranial Magnetic Stimulation (TMS) or transcranial Direct Current Stimulation (tDCS).

- TES treatment plan
  The patient begins an at-home TES protocol using the B.Stim device, typically involving daily sessions (e.g., 20–30 minutes) for around three weeks.
  → Treatments are self-administered but guided by medical prescription.

- Short-Term monitoring and adjustments
  Post-treatment evaluation assesses the effectiveness and any side effects of TES.
  → Adjustments to stimulation parameters, medication, or therapy may follow.

- Long-Term maintenance
  To prevent relapse, patients may continue with periodic maintenance sessions—e.g., one or two sessions per week every few months.
  → A home-based device like B.Stim allows more flexibility in scheduling and adherence.

- Ongoing follow-up with specialists
  Regular check-ins ensure sustained effectiveness, identify potential relapse, and allow treatment adaptations when necessary.

This patient journey illustrates that B.Stim's role becomes most valuable when traditional treatments fail to bring adequate relief, and when patients seek more autonomy in managing their mental health. The need for accurate diagnosis, effective guidance, and continued monitoring underscores the importance of professional oversight while still allowing flexibility for home-based use.

For B.Stim to be effective, it must integrate seamlessly into this care pathway, supporting the clinician's role while empowering the patient. Thoughtful design, clear guidance, and well-defined usage protocols will be key to ensuring that B.Stim is perceived as a safe, trustworthy, and meaningful tool in long-term depression management.

3.6. Requirements documents

As part of the design process, a Clinical Requirements Document (CRD) is created. The purpose of this document is to identify and define the clinical needs and constraints that the device must address, based on literature, expert consultation, and medical standards. This includes, for instance, safety, material choice, electronics, packaging, manufacturing, and patient-related needs.

Following this, a Functional Requirements Document (FRD) is created. This document builds upon the CRD and translates the clinical requirements into functional specifications that can guide the design and engineering of the device. It includes not only the clinical requirements but also expands them into technical, mechanical, and usability specifications that are measurable and verifiable.

This step ensures traceability from the clinical objectives to the actual design features, allowing for a user-centered and medically responsible development process. By structuring the requirements this way, the project maintains a strong alignment with both clinical effectiveness and practical feasibility in the final product.

3.6.1. Clinical Requirements Document

To compile the Clinical Requirements Document (CRD), an Excel spreadsheet (which can be found in Appendix B) is created based on Annex I of the Medical Device Regulation (MDR). Each requirement listed in this annex is systematically reviewed and evaluated for applicability to the B.stim device. Non-relevant items are excluded, while applicable requirements are reformulated in a clearer, design-oriented language to facilitate implementation in later stages.

The applicable requirements are then organized by category (e.g., safety, performance, usability) in a structured table (Table 3-1), allowing for better readability and easier integration into the subsequent Functional Requirements Document.

Table 3-1: Clinical requirements document

Category	Design Requirement	Cause/Problem/Context
Material & Composition	Consider material toxicity, flammability, compatibility, processing effects, mechanical properties	Ensure safety and compliance with CE standards
	Confirm chemical/physical properties	Verification of safety and reliability
Packaging	Minimize contamination/residue risk	Focus on tissues exposed frequently or for long durations
	Maintain packaging integrity for non-sterile products	Support for pre-use sterilization and cleanliness
Manufacturing	Minimize risks from particles (debris, degradation, residues)	Device must not pose chemical or physical hazards
	Restrict substances >0.1% w/w unless justified	According to Section 10.4.2; see referenced Excel sheet
Labelling	Reflect substance concentration compliance	Transparent disclosure for regulatory conformity
Design	Prevent unintended ingress of substances	Consider environment and intended use
	Reduce infection risks via design and process	Applies to patients, users, and handlers
	Facilitate cleaning, disinfection, sterilization	Ensure reusability and hygiene

	Ensure compatibility with other devices and prevent misconnections	Combination use safety
	Comply with Directive 2001/83/EC	Substance evaluation across various parameters
	Minimize risk of injury (physical, chemical, electrical, environmental)	Includes calibration, maintenance, and safe handling
	Avoid accidental ingress, fire, explosion	Consider single fault conditions
	Ergonomic measurement and display design	Align with user context and intended environment
	Enable safe disposal of device and waste	Environmental and user protection
Electronics & Software	Software must ensure performance, reliability, fault tolerance, security	Developed per state-of-the-art standards
	Design must consider mobile platform factors	Visual accessibility and external conditions
	Set IT/network/hardware/security requirements	Prevent unauthorized access and disruptions
	Reduce EMI and ensure EM immunity	Maintain device performance alongside other electronics
	Prevent accidental electric shock	Protection in all use scenarios including faults
	Minimize mechanical risks from movement/parts	Enhance stability and user safety
	Safe terminal and connector design	Minimize user handling risks
	Avoid errors in part fitting/refitting	Use intuitive design and clear instructions
	Control device surface temperatures	Avoid heat-related injuries
Energy/Substance Supply	Accurate delivery and monitoring of substances or energy	Avoid under/over delivery; prevent accidental release
	Clear and intuitive controls/indicators	Ensure operational understanding for users and patients
Use by Laypersons	Device must be safely usable and interpretable after training	Reduce risk of cuts, pricks, misuse, and misinterpretation
	Provide self-check capabilities to confirm function	Notify users if device performance fails

3.6.2. Functional Requirements Document

To create the Functional Requirements Document (FRD), the needs and wants identified during the interview phase are systematically reviewed and translated into concrete design requirements. This step bridges the gap between user insights and technical implementation.

The requirements are categorized according to different design goals, including rentability, customizability, user experience, and electronics. Within each category, the corresponding functional requirements are clearly formulated and compiled into a structured table (Table 3-2).

Table 3-2: Functional requirements document

Objective	Design Requirement	Cause/Problem/Context
Hygiene and Cleanability	Waterproof and water-resistant materials	Renting of B.Stim
	Switchable parts/electrodes	Detachable and replaceable parts like electrodes or pads for personal hygiene
	Waterproofing/resistance for cleaning	
User Experience	Customizability	
	Smooth surfaces with no hard-to-clean crevices	
	Have a good fit for every head size	
	As much freedom as possible for the placement of the electrodes	
	Adjustable straps or sizing mechanisms to fit various head shapes and sizes	
	Adjustable mechanism for placement of electrodes	
	(Possibility to add/remove electrodes)	
Electronics	Powered by battery	
	Headset is used correctly by every user	
	Intuitive design	
	Clear instructions for setup and use	
	Safety protocols to prevent misuse	
	Facilitate repairs	
	Facilitate replacement	
	Key components (e.g., electrodes, straps, or pads) should be easily replaceable for reuse and maintenance	
	System for periodic replacement of wear-prone parts	
Portability	Lightweight and compact design	
	Rechargeable battery to eliminate reliance on constant power sources	
	Good rental logistics	
	Durable, secure packaging for shipping between rentals	
Data Tracking	Erasing all data between rentals	
Electrodes	No visible wires	
	Rechargeable	
	Indicator for battery level	
	Method for applying electrodes as sustainable as possible	
	Good impedance	

3.6.3. Design requirements

The clinical and functional requirements outlined in the previous sections are synthesized and translated into a comprehensive set of design requirements. These requirements represent the essential characteristics the B.stim device must fulfill to be clinically effective, user-friendly, and suitable for rental deployment. Organized into thematic categories, these design requirements serve as the foundation for ideation and engineering, ensuring alignment with user needs, regulatory constraints, and technical feasibility.

3.6.3.1. Color, Materials, and Finishes (CMF)

- Toxicity and biocompatibility:
    - Materials must be non-toxic and compatible with biological tissues.
    - No release of harmful substances, wear debris, or residues under normal use.
- Durability:
    - Resistant to degradation, flammability, and adverse environmental effects.
- Surface quality:
    - Smooth surfaces with no hard-to-clean crevices.
    - Materials must withstand frequent cleaning and disinfection.
- Waterproofing:
    - Waterproof and water-resistant materials to facilitate hygiene.

3.6.3.2. Design and Ergonomics

- Customizability:
    - Adjustable straps or sizing mechanisms to accommodate various head shapes and sizes.
    - Freedom to adjust electrode placement for optimal use.
    - Support for adding or removing electrodes for personalized treatment.
- Comfort:
    - Lightweight and compact for portability and user comfort.
- Ease of Use:
    - Intuitive design with clear instructions for setup and operation.
- Durability:
    - Designed to minimize risks from physical features (e.g., cuts, pricks, moving parts).
- Fit:
    - Secure yet comfortable fit for extended sessions without slippage.

3.6.3.3. Hygiene and Maintenance

- Replaceable parts:
    - Detachable and replaceable electrodes and pads for personal hygiene.
    - System for periodic replacement of wear-prone parts.
- Ease of cleaning:
    - Components designed for easy cleaning, disinfection, and safe reuse.
- Rental considerations:
    - Durable and secure packaging for rental logistics.
    - Capability to erase all user data between rentals.

3.6.3.4. Electronics and Connectivity

- Safety:
    - Protective measures against accidental electric shocks.

    - Designed to avoid electromagnetic interference and maintain immunity.
- Reliability:
    - Electronic systems and software to ensure repeatability, reliability, and stable performance.
- Battery:
    - Rechargeable battery to eliminate reliance on constant power sources.
    - Lightweight and compact battery integration.
- Software and data security:
    - Software developed according to life cycle management, including verification and validation.
    - Data security measures to prevent unauthorized access or tampering.

3.6.3.5. User Safety

- Risk reduction:
    - Minimize risk of injury due to physical, electrical, or environmental factors.
    - Robust against foreseeable external influences and adverse environmental conditions.
- User protection:
    - Prevent microbial contamination of device components.
    - Ensure device remains safe under single fault conditions.
- User interface:
    - Clear indicators for device operation and adjustment parameters.
    - Ergonomically designed controls.

3.6.3.6. Performance and Functionality

- Measurement accuracy:
    - Ensure accuracy, precision, and stability in electrical stimulation.
- Interoperability:
    - Compatibility with other medical devices and IT systems.
    - Avoidance of negative interactions between software and IT environments.
- Energy delivery:
    - Accurate and safe delivery of electrical stimulation.
    - Safety mechanisms to prevent accidental release of energy.

3.6.3.7. Packaging and Disposal

- Packaging:
    - Packaging systems that maintain product integrity and cleanliness.
    - Designed to reduce microbial contamination during shipping.
- Sustainability:
    - Facilitate safe disposal of waste substances and the device at the end of life.

3.6.3.8. Regulatory Compliance

- Medical standards:
    - Conformance with Class III medical device standards for CE marking.
    - Compliance with chemical, biological, and mechanical specifications as per regulations.
- Documentation:
    - Comprehensive labeling and instructions to ensure safe use by laypersons.
    - Verification of device performance as intended.

By summarizing the clinical and functional insights into well-defined design requirements across domains such as materials, ergonomics, hygiene, electronics, safety, and regulatory compliance, a solid foundation is established for solution generation. This enables the next phase of the design process, ideation, where potential solutions can be explored

4 Define

4.1. How might we?

The “How might we?” (HMW) framework is used to translate insights from the discover phase into actionable design opportunities. By formulating design challenges as open-ended questions, the problem space is framed in a way that encourages creativity, user-centered thinking, and technical feasibility.

The following HMW questions are made from the synthesis of:

- Literature on depression, TES, and MDR
- Expert and patient interviews
- Benchmark analysis of existing TES devices
- Functional and clinical requirement documents
- The patient journey and use context

4.1.1. Framing questions

The following questions cover the main aspects of the product and service:

- How might we ensure that B.stim is perceived as safe and trustworthy for home use?
    - Based on users’ concerns about brain stimulation and safety.

- How might we balance user freedom and clinical safety in stimulation settings?
    - Controlled flexibility was a major concern from stakeholders.

- How might we design for different head shapes and electrode configurations?
    - Tied to ergonomic and usability requirements.

- How might we position and sell the product to both patients and professionals?
    - Based on discussions about B2B, B2B2C and B2C during interviews

- How might we encourage trust and regular use through product aesthetics and app design?
    - Usability and appearance matter for adoption and compliance.

These questions guide the define and develop phases by focusing ideation on validated user needs and practical constraints. These questions serve as a good design problem which will be solved in the next steps.

4.2. Persona

To design an effective, user-centered medical device like B.stim, it is essential to understand the needs, behaviors, and preferences of the target user. A persona serves as a fictional but evidence-based representation of a typical user, helping to humanize abstract data and guide design decisions. By creating a persona, insights from interviews and literature can be translated into a concrete profile that embodies the motivations, frustrations, and lifestyle context of potential users. This allows for more empathetic design choices and ensures that usability, functionality, and aesthetics align with real-world expectations. The persona helps keep the end-user in focus throughout the development process, especially when making trade-offs in features, form factor, or user interaction.

To develop the persona, data collected during the discovery phase is used. This included literature research on patients with depression, interviews with mental health professionals, and conversations with individuals from the target group. Common themes were identified, such as dissatisfaction with traditional treatment, interest in alternative solutions, and the importance of ease of use in mental health technologies. These findings were then distilled into a clear, representative persona: Alex—a tech-savvy young professional with mild to moderate depression, searching for a scientifically backed, user-friendly solution to integrate into daily life.

4.2.1. Alex

Name: Alex
Age: 27
Height: 170 cm
Occupation: Marketing Consultant
Mental health: Mild to moderate depression, occasional anxiety

Alex is a busy professional balancing work, personal life, and mental well-being. She has been experiencing mild to moderate depression or anxiety, but she's not interested in traditional medication due to side effects. Alex has tried meditation and therapy, but they're looking for something more scientific, effective, and convenient to integrate into their daily routine.

Alex is tech-friendly and willing to try biohacking or wellness technology, especially if it's easy to use, backed by science, and fits into their lifestyle.

Treatment History:
In therapy for over a year
Tried multiple antidepressants; discontinued due to side effects (e.g. fatigue, emotional numbness)
Open to alternatives that are less invasive and more lifestyle-friendly

Goals & Motivations:
Maintain productivity and focus at work
Regain emotional balance without relying on daily medication
Use tools that support long-term well-being
Try methods backed by science, not just wellness trends

Frustrations:
Medication side effects
Lack of time for long therapy sessions

Stigma around mental health devices
Overwhelming mental load of managing treatment alone

Technological Comfort:
Uses wearable tech like Fitbit or Apple Watch
Follows podcasts and blogs on mental performance and biohacking
Values good UX and product design
Prefers mobile-first experiences and remote support

Lifestyle:
Works 40-50 hours/week, often from home
Exercises lightly 2–3 times a week
Lives alone in an apartment in the city
Regularly tries new wellness or productivity tools

The persona of Alex plays a guiding role throughout the ideation and development phases. By anchoring design decisions to her needs and constraints, it ensures the concept remains grounded in real user scenarios.

4.3. Business Case

To determine a viable path to market, several business scenarios were explored in response to the guiding question: 'How might the product be positioned and sold to both patients and professionals?'. This inquiry emerged from discussions with stakeholders and was grounded in the need to evaluate different commercialization strategies, such as B2B, B2B2C, and B2C. Understanding the implications of each model was essential to ensure alignment with clinical practices, user needs, and ethical distribution.

A comparative analysis was conducted by mapping out multiple business scenarios. For each model, a schematic overview was created to visualize the key stakeholders and relationships within the ecosystem. These models were then presented and discussed with relevant stakeholders. Feedback was gathered to assess the feasibility, ethical concerns, and potential risks associated with each approach. Notably, one stakeholder raised concerns about a direct sales model targeting specialists, warning that it may lead to biased prescribing behavior due to commercial incentives.

The business scenarios are:

- Direct purchase B2C (Figure 4-1)
- Direct purchase B2B (Figure 4-2)
- Subscription/rental model (Figure 4-3)
- Pay per session model (Figure 4-4)
- Alternative for rental/pay per session model (Figure 4-5)

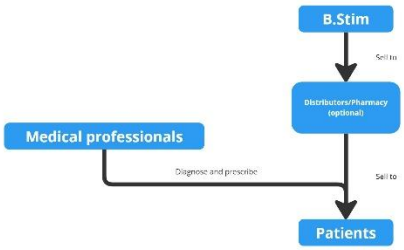

Figure 4-1: Direct purchase B2C

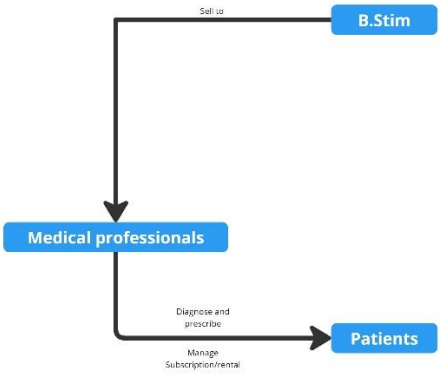

Figure 4-2: Direct purchase B2B

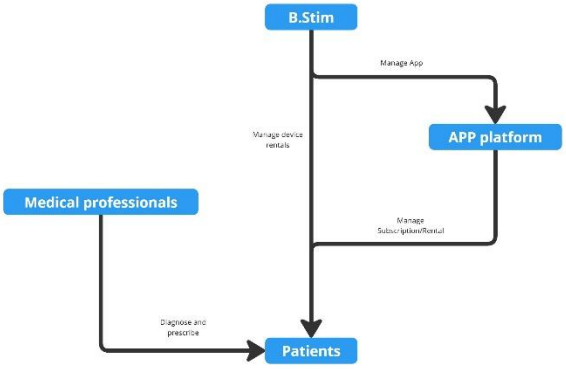

Figure 4-3: Subscription/rental model

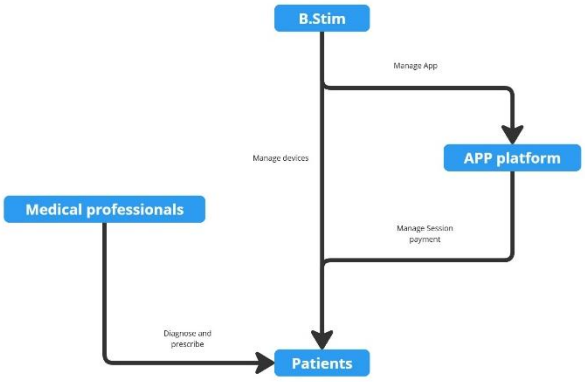

Figure 4-4: Pay per session model

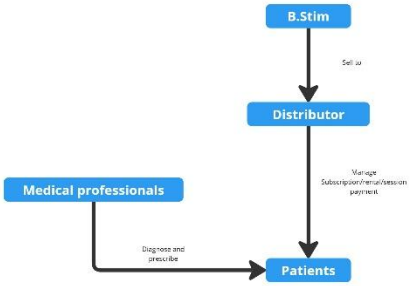

Figure 4-5: Alternative for rental/pay per session model

Based on stakeholder feedback and analysis of user affordability, a rental-based business model was selected as the most suitable option. This approach addresses cost barriers for individual users and enables devices to be returned and reused after treatment, enhancing sustainability and reducing product abandonment. The chosen model supports ethical access to the device while facilitating controlled distribution. This outcome informed subsequent steps, such as the service blueprint and pricing structure, which were tailored to reflect the selected rental model.

4.4. Service blueprint

To gain a comprehensive understanding of where B.stim fits within the broader mental health treatment journey, a service blueprint was developed. This tool served to map out the interactions between the patient, healthcare providers, and the B.stim system across different stages of diagnosis and treatment. The goal was to visualize the full service delivery process, identify potential pain points, and ensure alignment between the product and the ecosystem in which it would be deployed. In doing so, the blueprint supported the design of a coherent, user-centered service that integrates seamlessly with existing clinical workflows.

The blueprint (Figure 4-6) was constructed by aligning the typical patient journey—ranging from symptom recognition to long-term follow-up—with corresponding actions, technologies, and physical evidence relevant to the B.stim service.

Key touchpoints were identified, such as patient consultations, prescription moments, and device usage. For each stage, potential contributions of B.stim were visualized in terms of actions (e.g., device delivery, data sharing, maintenance), technological infrastructure (e.g., mobile app, specialist portal), and physical evidence (e.g., reports, prescription slips). This visual framework was validated through expert input to ensure realism and relevance. The rental model previously defined was also incorporated into the blueprint, emphasizing device reuse and patient support throughout the treatment period.

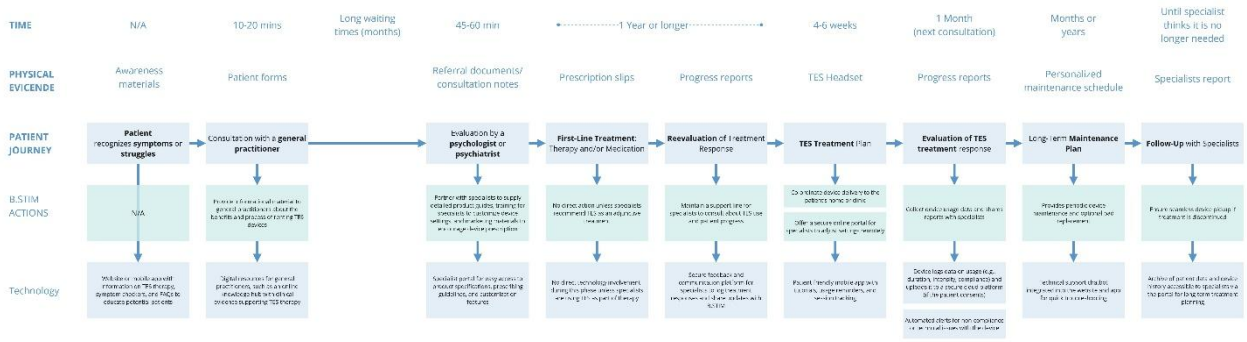

Figure 4-6: Service blueprint

The service blueprint, which can be read in detail in Appendix C, provided a clear and structured overview of how B.stim can be integrated into the mental healthcare pathway. It highlighted key opportunities for patient engagement, clinician support, and technological integration, while revealing critical moments for intervention and feedback. This mapping exercise informed further development of the patient interface, app features, and specialist collaboration tools.

4.5. Concept Sketches

Concept sketching was employed as a rapid and cost-effective method to explore a wide range of form factors and configurations for the B.stim headset. The goal of this step was to translate abstract functional and user requirements into tangible design directions. Sketches enabled the visualization of possible solutions early in the design process, allowing for iterative thinking and facilitating communication with stakeholders. This step played a critical role in identifying promising design elements and in initiating discussions around usability, comfort, and aesthetics.

Multiple rounds of quick, low-fidelity sketches were produced (Figure 4-7) , each representing different design directions for the headset and modular electrodes. The variations focused on aspects such as adjustability, electrode placement, headband configurations, and aesthetic appeal. These initial concepts were created based on insights from earlier research phases, including the persona and service blueprint. Sketches were then used in discussions with users and experts to gather preliminary feedback. Particular attention was given to ensuring ergonomic fit, ease of use, and compatibility with the electronic and electrode components planned for integration.

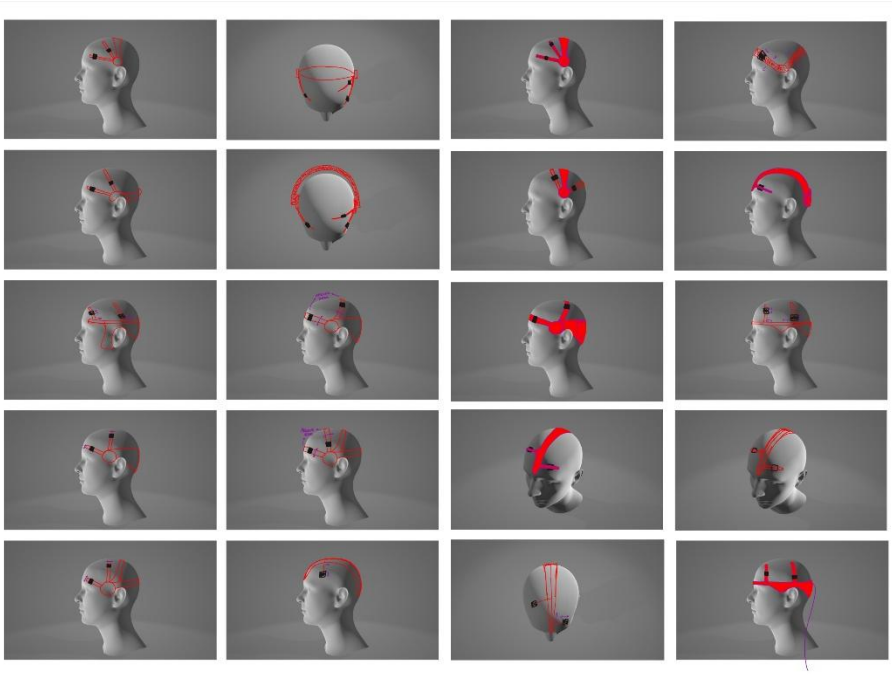

Figure 4-7: Concept sketches

The concept sketches provided an essential foundation for design decision-making by making abstract ideas visible and comparable. Feedback obtained through stakeholder discussions helped to identify recurring preferences and concerns, such as the importance of a simple design, unobtrusive form and straightforward electrode placement. These insights guided the selection of three representative headset concepts and three electrode types for further development in the prototyping phase. The next step is to narrow the concepts down to some final concept ideas.

4.6. Viscom Phase I

Following the initial concept sketching, an additional ideation phase was done through AI usage. The purpose of this phase was to gain additional design inspiration, explore aesthetics more deeply, and facilitate clearer communication of the concepts. By generating photorealistic AI generated images, this step allowed for early assessment of form, proportions, material expressions, and user interaction cues, which are not always fully captured in hand-drawn sketches.

The previously developed concept sketches were uploaded to an AI-based visualization platform, Viscom, which transforms sketches into photorealistic renders (Figure 4-8). Each concept was accompanied by descriptive prompts to guide the output toward realistic and context-appropriate representations. The generated images provided a more immersive impression of the potential product, making it easier to reflect on surface details, material finishes, and how the headset might appear in use. These visuals were reviewed internally and used to inspire further iteration and refinement.

Figure 4-8: Viscom generated images

Viscom Phase I contributed to the ideation process by enhancing the visual clarity and realism of the early concepts. It enabled a more concrete evaluation of design choices and supported further development by uncovering new ideas and visual directions. The rendered images also served as valuable material for stakeholder discussions and design reviews. The output of this phase was used to guide the selection of concepts for physical prototyping and usability testing in the next stage.

4.7. AI Ideation

To broaden the range of design possibilities and stimulate unconventional thinking, an AI-based ideation step is included in the early concept development phase. This method aims to generate out-of-the-box ideas that may not arise through traditional brainstorming or sketching techniques. The objective is not necessarily to produce directly feasible solutions, but rather to explore unexpected visual directions and conceptual interpretations that can inspire further refinement of the design.

A generative AI tool is used to create photorealistic product concepts (Figure 4-9) based on a detailed prompt describing the functional and aesthetic requirements of the B.stim headset. The input includes information on key specifications such as electrode configuration, intended use context, and interaction methods. The generated outputs are reviewed for their creative value, with particular attention to form factors, material expressions, and interaction features. While many of the resulting concepts present technical or ergonomic challenges that render them non-functional, they serve as visual provocations and stimulate new ideas.

Figure 4-9: AI generated ideation images

The AI ideation step contributes to the creative process by expanding the visual and conceptual design space. Although most generated outputs are not directly applicable, they provide inspiration for alternative forms, structures, or interface approaches that may be adapted into more practical designs. This step complements traditional sketching and analytical tools by injecting a level of unpredictability and novelty into the ideation phase. Insights and visual elements derived from this process are selectively incorporated into future concept generation.

4.8. Morphological map

A morphological table is used to systematically explore a wide range of technical and functional variations for the B.stim headset. This method supports divergent thinking during the concept development phase and helps identify viable combinations of product features. The goal is to ensure all critical functional components, such as electrode type, battery setup, interface design, and sizing mechanism, are considered in a structured and comparative way.

Key product features are listed along one axis of the table, with multiple conceptual solutions proposed for each feature along the other axis. The table can be read in Appendix D. These alternatives include variations in electrode configuration, materials, power source, data transmission, user interface, and contact mechanisms. The table is built based on insights from previous research, design constraints, and benchmarking. This structured format allows for the identification of compatible combinations, which can then be further evaluated.

The morphological table provides a comprehensive overview of potential product architectures and serves as a foundation for objective evaluation. It functions as a decision support tool and guides the transition from broad exploration to focused selection. The next step consists of assessing the proposed combinations using a weighted decision matrix to determine the most suitable configuration for development.

4.9. Weighted Decision Matrix

A weighted decision matrix is applied to objectively evaluate and compare the component alternatives identified in the morphological table. This method supports rational and transparent selection by incorporating both design criteria and stakeholder preferences. The aim is to determine the most promising concept configuration that balances technical feasibility, user needs, and production constraints.

Each alternative is scored against defined evaluation criteria, such as user comfort, ease of use, customizability, safety, battery life/power consumption, durability and maintenance, and connectivity and feedback (Figure 4-10). These vary with every feature because then don't always apply to every one. Weighting factors are assigned to each criterion based on their relevance, as established through stakeholder consultation with stakeholder Laís. Total scores are calculated for each configuration, and the results indicate which options align most closely with the design priorities. The full matrix can be read in Appendix E.

	Feature:	Type of sensors/electrodes			
Criteria	Weight	Dry electrodes	Pads with saline solution	Sponges with saline solution	
User comfort	4	5	4	4	
Ease of use	3	5	2	2	
Customizability	4				
Safety	3	4	5	5	
Battery life	2				
Durability and maintenance	1	5	2	2	
Connectivity & feedback	2				
	Total:	52	39	39	0

Figure 4-10: Example of weighted decision matrix

By applying the matrix to the alternatives presented in the morphological table which can be read in Appendix F, a systematic selection process is established. This approach ensures that each design element is not evaluated in isolation, but rather in relation to the overall product configuration and its intended use context. The result is a validated combination of components that balances performance, usability, and feasibility, forming a solid foundation for the next development stage.

4.10. Concept Ideas and Specifications

To transition from the ideation phase to the development phase, a selection of three final concepts is established. This step serves to narrow down the design direction and define the technical and functional parameters for further development. The aim is to ensure that each selected concept reflects a coherent integration of design features, aligns with user needs, and is feasible within the project constraints. Finalizing the specifications also facilitates a structured and comparable development process for the upcoming prototyping and testing phases.
Based on the outcomes of the weighted decision matrix and insights gained from sketching, visualizations, and stakeholder input, three distinct concept directions are selected. Each concept represents a different approach to form, interaction, or modularity, while all comply with the key functional requirements identified earlier. For each of the three concepts, the relevant components and features—such as electrode type, user interface, sizing mechanism, and power supply—are defined based on the highest-scoring combinations in the morphological matrix. These specifications are documented and serve as fixed parameters for subsequent CAD modeling and physical prototyping.

4.10.1. Concept 1

This concept uses a glasses-style positioning mechanism, where the main component rests on the ears and connects across the front of the forehead. From this central unit, three flexible bands extend over the top of the head. Each band is individually rotatable from a joint integrated into the main component, allowing for adjustable electrode placement across a wide range of positions. The concept is designed to offer high flexibility in electrode configuration without compromising comfort or wearability. The electrodes slide along the bands, enabling freedom in electrode placement. Sizing is adjusted via a headphone-style sliding mechanism embedded within the arms of the main component. This concept is sketched in figure 4-11.

Key Specifications

- Electrode positioning: three individually rotatable bands enable varied electrode placement.
- Attachment mechanism: slide-in-place system for electrode modules.
- Sizing mechanism: headphone-style adjustment integrated into side arms.

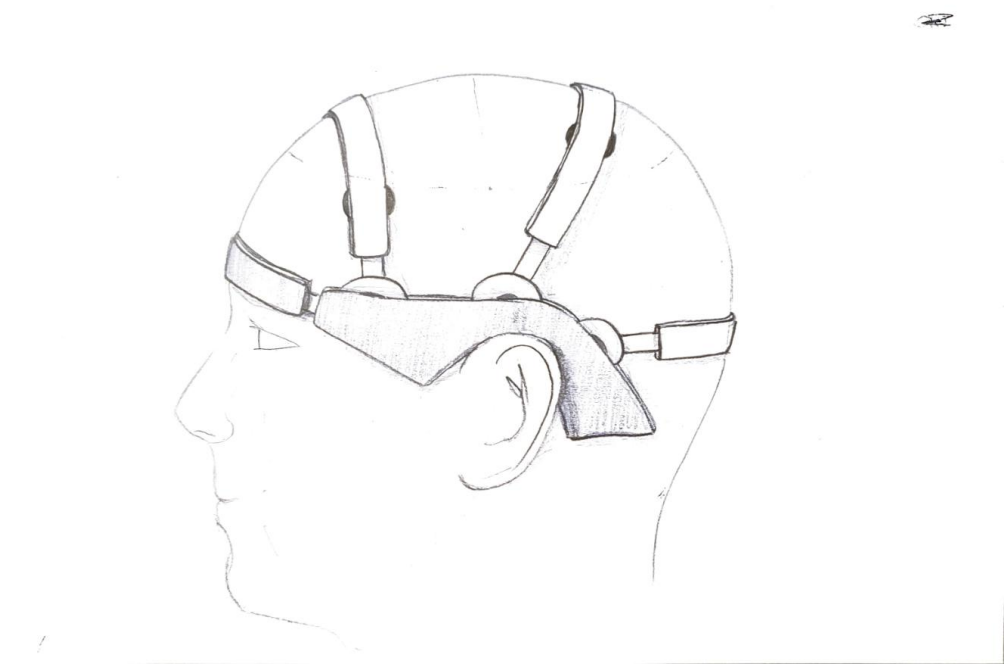

Figure 4-11: Concept 1 sketch

4.10.2. Concept 2

The second concept is inspired by over-ear headphone geometry. The main structural component spans across the top of the head and establishes firm contact with the skull via two lateral pressure points positioned above the ears. From this core unit, two additional bands extend—one toward the forehead and one toward the back of the head. These bands are rotatable and can be used to place electrodes as well as on the main band. The pressure points act as rotational joints for the bands, allowing flexibility in positioning. A headphone-style sizing mechanism allows the main component to adjust to different head sizes. This concept is sketched in figure 4-12.

Key Specifications

- Electrode positioning: three zones—main band, front band, and back band.
- Attachment mechanism: slide electrodes along band.
- Sizing mechanism: headphone-style telescopic side extension.

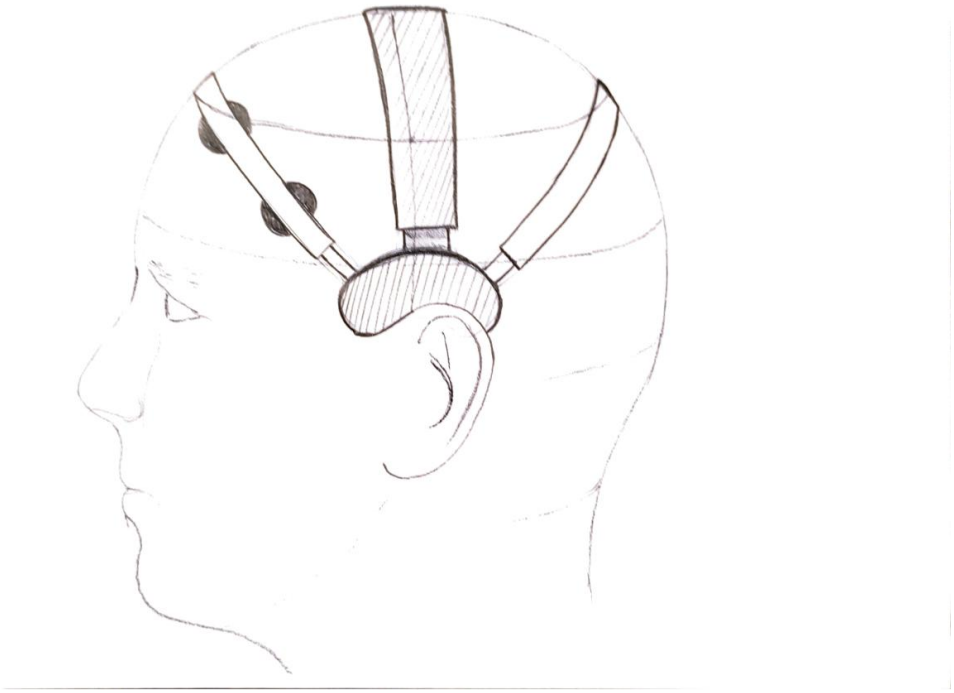

Figure 4-12: Concept 2 sketch

4.10.3. Concept 3

This concept uses a minimal structural approach consisting of two interconnected bands joined at the center with a rotational joint. The two bands can pivot from 0° to 180° relative to each other, creating full coverage for flexible electrode placement. Electrodes can be positioned freely along both bands, supporting a wide range of configurations. The joint mechanism allows the structure to fold compactly for storage or adapt to varying head geometries. This concept prioritizes simplicity and configurational freedom. This concept is sketched in figure 4-13.

Key Specifications

- Electrode positioning: full freedom of placement along both bands.
- Attachment mechanism: slide-on rail placement along tracks.
- Sizing mechanism: headphone style sizing mechanism via the central rotational joint.

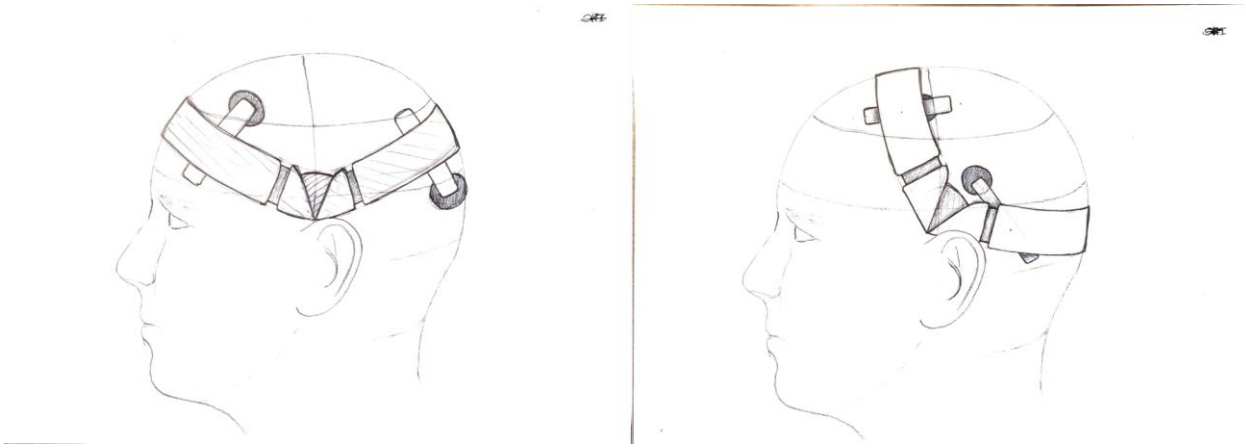

Figure 4-13: Concept 3 sketch

This step results in three clearly defined concept proposals. The selection ensures diversity in design while maintaining technical feasibility and alignment with user expectations. These concepts form the basis of the develop phase, in which physical prototypes are produced and evaluated through user testing and technical analysis.

4.11. MoSCoW Analysis

To gain clear insight into the priorities of key stakeholders and to define the direction of the development phase, a MoSCoW analysis is conducted. This method categorizes requirements into four levels of importance: Must have, Should have, Could have, and Won't have. This provides a structured overview of which features and goals are critical for the success of the B.stim project. The analysis supports informed decision-making by aligning technical development and user experience design with stakeholder expectations.

The analysis is conducted in collaboration with clinical stakeholder Lais, who independently prioritizes the design factors based on her expectations for the B.stim project. In doing so, she takes into account both the clinical relevance and usability of the device, as well as the academic context of the thesis. This ensures that the identified priorities align with both stakeholder needs and the realistic scope of the thesis. Each key design challenge is placed into one of the MoSCoW categories accordingly (Figure 4-14).

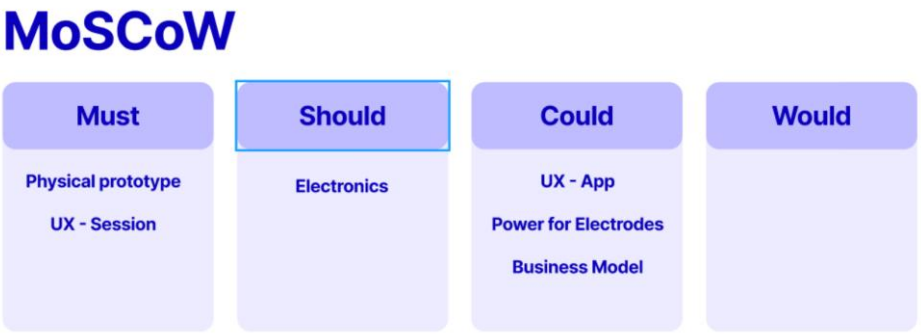

Figure 4-14: Moscow analysis

5 Develop Phase I

The first development phase aims to translate conceptual ideas into tangible prototypes, enabling early-stage validation of form, fit, usability, and user interaction. The primary goal is to compare the three selected design directions and

electrode variations in a low-fidelity format, allowing rapid feedback collection and refinement before more complex prototyping.

5.1. Quick and dirty prototypes

To gain an early understanding of the spatial configuration, ergonomics, and handling of the selected concepts, a series of low-fidelity prototypes is constructed. This step aims to translate abstract design ideas into tangible models, allowing for quick evaluation of form, scale, and functional assumptions. Early physical exploration also supports intuitive feedback that is not easily captured through sketches or digital visualization, thereby informing adjustments before committing to more advanced prototypes.

Each of the three concepts selected in the define phase is prototyped using readily available materials, including cardboard (Figure 5-1), split pins (Figure 5-2), and disposable wooden sticks (Figure 5-3). These materials enable quick assembly and allow for basic articulation and movement. The prototypes are scaled according to the designer's own head measurements, allowing for direct and immediate evaluation of fit, reach, and flexibility in electrode positioning. Particular attention is given to testing the intended movement of bands, the adjustability of sizing mechanisms, and the potential comfort of the form factors. The simplicity of the models allows for rapid iteration and side-by-side comparison.

Figure 5-1: Cardboard

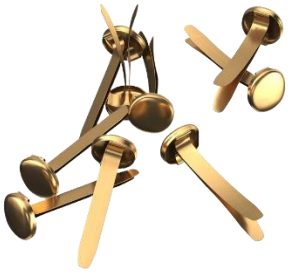

Figure 5-2: Split pins

Figure 5-3: Disposable wooden sticks

5.1.1. Concept 1

Figure 5-4: Cardboard prototype concept 1

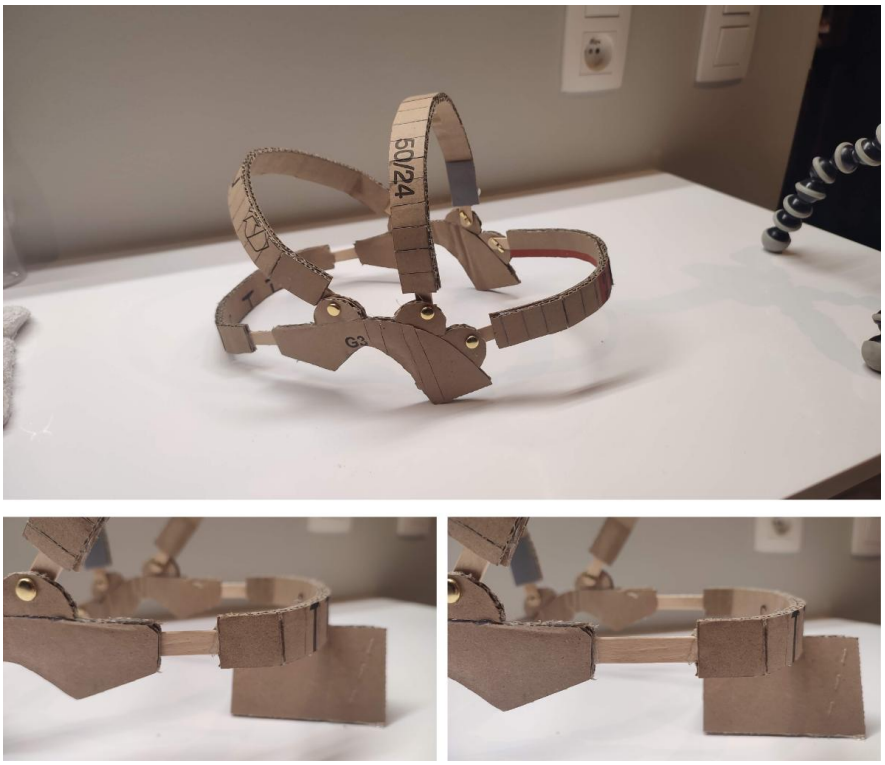

Figure 5-5: Details of prototype concept 1

5.1.2. Concept 2

Figure 5-6: Cardboard prototype concept 2

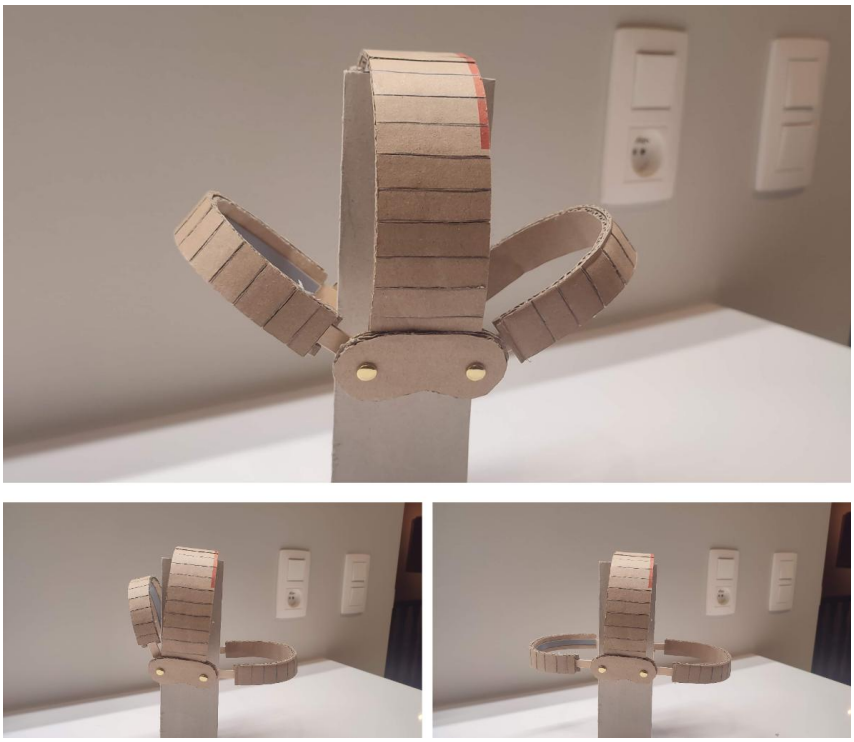

Figure 5-7: Details of prototype concept 2

5.1.3. Concept 3

Figure 5-8: Cardboard prototype concept 3

Figure 5-9: Details of prototype concept 3

5.1.4. Electrodes

Alongside the headset prototypes (Figures 5-4, 5-5, 5-6, 5-7, 5-8, 5-9), three electrode types are constructed in simplified form:

- A regular electrode like it is currently used in TES devices, with a surface of around 20-25cm² (Figure 5-10)
- An extended arm electrode allowing greater reach or offset placement. (Figure 5-11)
- A high-definition electrode with the anode or cathode in the middle which is then surrounded by an array of the opposite electronic pole. (Figure 5-12)

5.1.4.1. Regular electrode

Figure 5-10: First prototype regular electrode

5.1.4.2. Extended arm electrode

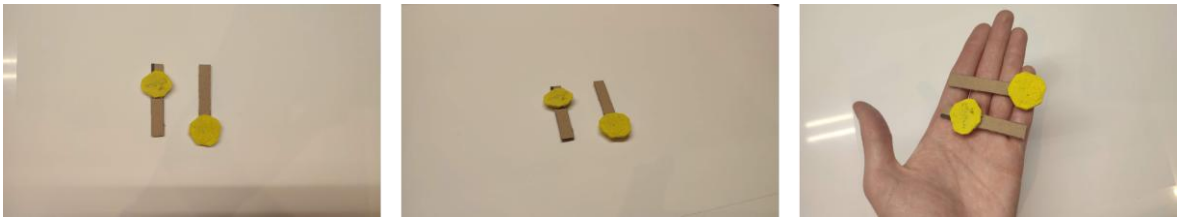

Figure 5-11: First prototype extention arm electrode

5.1.4.3. High Definition electrode

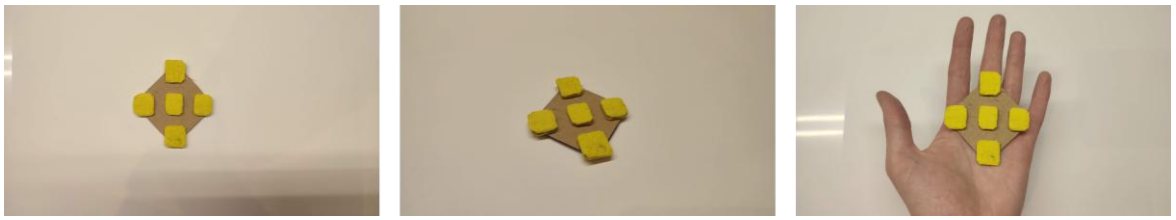

Figure 5-12: First prototype high definition electrode

These variations are compared for their integration potential, placement versatility, and expected user comfort when attached to the respective headset concepts. (Figure 5-13)

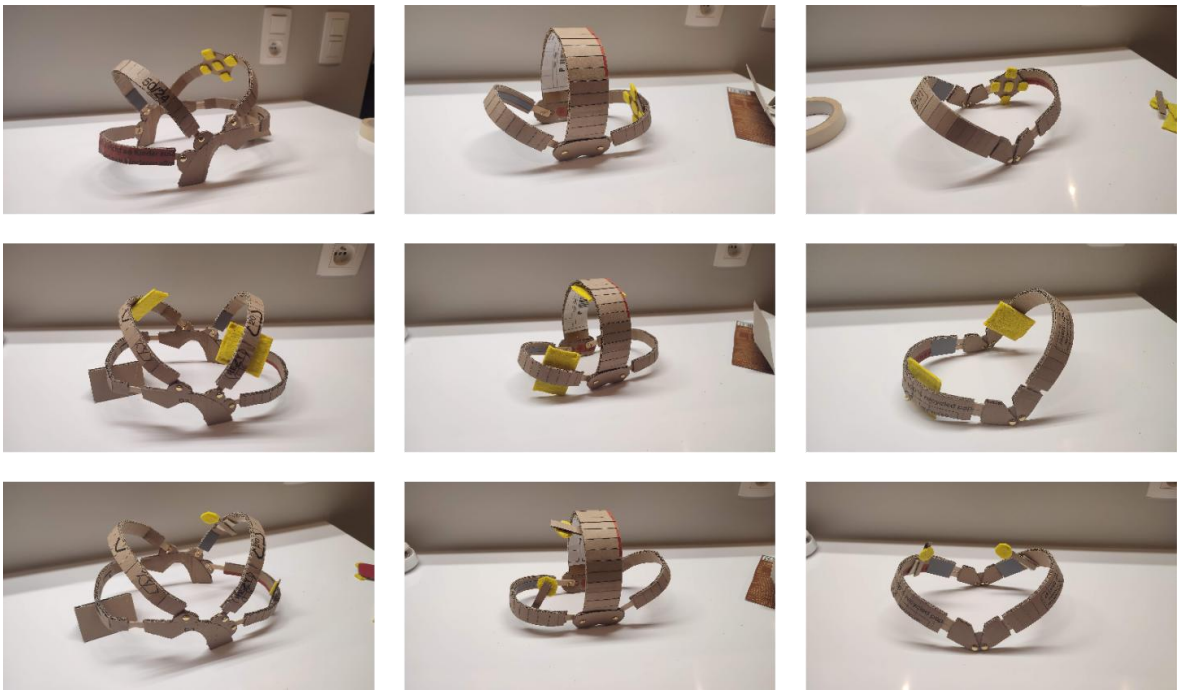

Figure 5-13: Electrodes attached on concepts

The quick and dirty prototypes provide immediate insights into the physical feasibility of each concept and reveal limitations that are not apparent in drawings or digital renderings. Differences in adjustability, contact points, and stability become more evident, guiding refinement decisions for the next development stage. The outcomes of this step inform which design features require modification, simplification, or validation through higher-fidelity prototyping.

5.2. Selection of final concept

To determine which of the three developed concepts would be advanced into the final design and development phase, a structured evaluation is conducted. The goal is to select the concept that best balances usability, technical feasibility, user preferences, and stakeholder expectations. This selection process ensures that the design direction is well-informed, justified, and aligned with the overall project goals.

Three evaluation methods are used to assess the concepts:

- Usability testing
- SWOT analysis
- Stakeholder feedback

5.2.1. Usability Testing:

Participants are asked to interact with each headset prototype and perform tasks such as adjusting the fit, positioning electrodes, wearing the device, and moving while wearing it. They are also asked to rank the headsets by usability preference and professional appearance. Observations and verbal feedback (think aloud protocol) are used to identify usability issues and confusing elements.

5.2.1.1. Protocol

Objective:
To evaluate and compare the usability, comfort, and perceived professionalism of three B.stim headset prototypes based on participant interaction and subjective feedback.

Participants:
Target group includes users representative of the intended end-users (e.g. adults familiar with wearable technology and mental health devices).

Materials:

- Three low-fidelity headset prototypes (Concept A, B, C)
- Task list
- Observation notes app

Procedure:
Introduction
Briefly explain the purpose of the test.
Tell them about the think aloud protocol and ask them to perform this during the test.
Instruct the participant that they will try on three different headset prototypes and complete a set of simple tasks for each.

Task-Based Evaluation (repeat for each headset):

A) Adjust the device to fit comfortably on the head.
B) Position an electrode on three target areas of the head (region A, B, and C).
C) Wear the device for several minutes and describe how it feels.
D) Move around (e.g. stand up, walk a few steps) while wearing the headset to evaluate stability and comfort.

Ranking and Feedback
After testing all three prototypes, ask the participant to:

A) Rank the headsets from most to least preferred based on overall experience and willingness to use.
B) Rank the headsets from most to least professional in terms of visual appearance.
C) Explain the reasoning behind their rankings.

Data Collection:
Record observations of participant behavior, difficulties, and adjustments.
Capture direct quotes and feedback.
Collect ranking data for quantitative comparison.

Outcome:
Findings are used to identify usability issues, assess user preference, and support concept selection for further development.

5.2.1.2. Conclusion

The usability testing reveals clear distinctions in user experience across the three prototypes. Concept 1 is perceived as confusing due to the high number of adjustable components, which complicates fitting and electrode placement. Concept 2 presents challenges in electrode positioning, particularly in achieving consistent contact in the intended regions. Concept 3 receives the most positive feedback from participants, ranking highest in both overall preference and perceived professionalism. Users report that this concept offers the most intuitive handling and visual appeal, making it the preferred option for further development.

5.2.2. SWOT Analysis:

To support the selection of a final concept for further development, a SWOT analysis is conducted. This strategic tool is used to assess each prototype across four categories:

- Strengths: Characteristics that function well or offer a competitive advantage
- Weaknesses: Limitations or internal shortcomings in the current design
- Opportunities: External possibilities for improvement or enhancement
- Threats: Potential risks or challenges that may hinder implementation or acceptance

This method allows for a structured evaluation of each concept's design potential, helping to identify not only what works, but also which areas require refinement.

5.2.2.1. Strengths

Concept 1:
Offers extensive adjustability and full-head coverage, allowing for highly flexible electrode placement. This adaptability is a core strength, especially in clinical contexts where individual customization is required.

Concept 2:
Is noted for its simple and intuitive design. Its structure is familiar and easy to handle, which enhances user confidence and reduces the risk of misuse.

Concept 3:
Performs strongly in terms of comfort and aesthetics. Its clean and minimal form factor contributes to a professional appearance and a positive first impression.

5.2.2.2. Weaknesses

Concept 1:
Is perceived as overly complex due to the large number of adjustable components. The high degree of configurability leads to confusion during setup and presents compatibility issues with glasses.

Concept 2:
Lacks configurational flexibility, offering fewer electrode placement options than the other designs. Additionally, the form factor is considered visually basic and less advanced.

Concept 3:

Has limited electrode placement freedom in its current form. The simplified band system may restrict therapeutic effectiveness if placement cannot be adequately adapted to clinical protocols.

5.2.2.3. Opportunities

Concept 1:
Has unused potential in utilizing the front band for additional electrode positions, increasing its therapeutic range.

Concept 2:
Could be improved by drawing inspiration from over-ear or headphone designs, which may increase user acceptance and better integrate the necessary electronics.

Concept 3:
Presents an opportunity for modular enhancement. By incorporating a modular electrode system, the concept could maintain its visual simplicity while significantly improving configurational flexibility.

5.2.2.4. Threats

Concept 1:
Risks becoming impractical due to its complexity. The abundance of adjustable parts and straps may overwhelm users and complicate manufacturing or maintenance.

Concept 2:
Faces challenges in integrating electronic components into its compact form. Enabling both electrode support and component housing within a slim headband could limit feasibility.

Concept 3:
May suffer from inconsistent or inaccurate electrode placement if sufficient positional guidance is not built into the system, potentially compromising the effectiveness of treatment.

The SWOT analysis provides a structured and comparative overview of the three concepts. Concept 1 excels in flexibility but is hindered by complexity. Concept 2 prioritizes simplicity and intuitiveness but at the expense of configurational options. Concept 3 is strongest in comfort and aesthetics, with clear opportunities for functional improvement through modularity. This analysis supports the integration of design strengths and mitigation of identified threats in the selection and refinement of the final concept.

5.2.3. Stakeholder Feedback:

To ensure that the final concept selection aligns with both clinical expectations and the academic objectives of the thesis, direct feedback from key stakeholders is collected. This step serves to validate previous findings, gain additional insight on both functional and aesthetic aspects of the concepts, and confirm that the chosen direction is feasible and relevant from the perspectives of both professional application and product development.

The results of the usability testing and SWOT analysis are compiled and presented to two key stakeholders: clinical expert and founder Laís and thesis promotor Bas. The three concepts are discussed in detail, with attention given to both user interaction and technical implementation. Stakeholders are invited to give their opinion on each concept, evaluating them from a functional point of view—such as usability, electrode placement potential, and integration feasibility—as well as from an aesthetic perspective, including professional appearance and visual appeal. Based on

their input, strengths and concerns are further clarified, especially with respect to the practical application of the device in a clinical and home environment.

Following stakeholder consultation, concept 3 is selected as the preferred final concept. Its simplicity, comfort, and professional appearance are identified as strong advantages. However, stakeholders stress that this concept should only move forward under the condition that a viable solution is developed to achieve full electrode placement freedom, comparable to the flexibility offered by the other concepts. This outcome defines the design challenge for the next development phase.

6 Develop Phase II

The second development phase focuses on transforming the selected concept into a modular and scalable system by selecting suitable connection and sizing mechanisms, refining the form factor, and validating modular electrode compatibility. This phase bridges early prototyping and technical feasibility by introducing design-for-assembly and component fit considerations.

6.1. Modular Electrode System

During the concept selection phase, Concept 3 was chosen as the final design direction due to its simplicity, comfort, and aesthetic quality. However, a critical condition imposed by stakeholders was the requirement for full flexibility in electrode placement, a feature that was more strongly supported in the other concepts. To meet this demand while retaining Concept 3's core strengths, a decision is made to incorporate a modular electrode system.

This decision directly addresses the functional requirement for “as much freedom as possible for the placement of the electrodes”, as defined in the Functional Requirements Document. It also supports the “How might we…” challenge:

“How might we design for different head shapes and electrode configurations?”

The modular system consists of connection mechanisms integrated along the full length of the bands, enabling users to position electrodes according to the prescribed stimulation montage. The connection mechanism is compatible with different electrode types—such as standard sponge electrodes, extended arm electrodes, and high-definition configurations—ensuring clinical adaptability and personalization.
This approach was informed by:

- Usability testing, which highlighted the importance of intuitive and flexible positioning.
- Benchmarking, where many devices lacked flexibility in placement of electrode locations.
- Stakeholder feedback, which emphasized configurational adaptability as essential for clinical effectiveness.

The integration of a modular electrode system allows the chosen concept to meet a core clinical and usability requirement without compromising its minimalist form factor. This strategy leverages design flexibility to support personalized treatment protocols and offers a scalable platform for future electrode innovation. The modular approach will be carried forward into the CAD and prototyping stages for technical refinement and user validation.

6.2. Connection mechanism

Following the decision to implement a modular electrode system—designed to allow flexible placement and interchangeability of various electrode types—a suitable connection mechanism must be selected to support this functionality. The connection method plays a critical role in enabling the modular design to function effectively, directly

impacting the product's usability, safety, and clinical reliability. It determines how easily users can attach, detach, or reposition electrodes along the headset, and therefore influences the overall hygiene, ease of maintenance, and precision of treatment. To ensure that the modular approach aligns with the broader goals of the B.stim headset, the connection mechanism must be carefully evaluated against the functional requirements established earlier in the development process.

A comparative analysis is conducted across six connection mechanisms (Figure 6-1):

- Magnetic connectors
- Pogo pins
- Slide-in rail system
- Pin and socket connectors
- Twist-lock connectors
- Clamp-on and clip-on systems

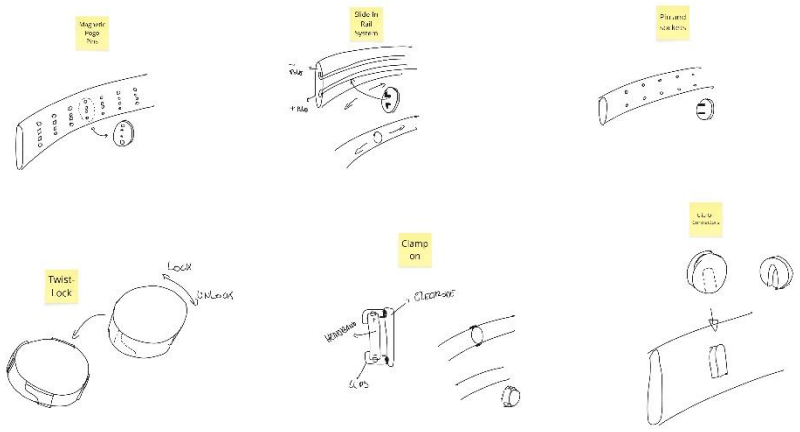

Figure 6-1: concept sketches of connection mechanisms

Each mechanism is evaluated based on six key criteria: ease of use, ingress protection, safety, performance/connectivity, hygiene, and stability. The ratings are informed by the functional requirements of the product and are represented in a scoring table (Figure 6-2).

The selected criteria are directly linked to the established functional requirements as follows:

Ease of use:
This criterion relates to the functional requirement of intuitive design and operation (Design and Ergonomics). A connection system must allow users to attach and remove electrodes without confusion, supporting independent use and minimizing errors during setup.

Ingress protection:
Linked to waterproofing and hygiene (Hygiene and Maintenance), this factor assesses how well the connector resists moisture, sweat, or contaminants. Good ingress protection is essential to maintain safe and hygienic reuse, especially in a rental model.

Safety:
This reflects the requirement for risk reduction and user protection (User Safety). The connector must prevent accidental detachment or electrical shock and remain safe under normal and fault conditions.

Performance / connectivity:
This criterion supports the requirement for reliable and accurate energy delivery (performance and functionality). A secure electrical connection is vital for consistent stimulation output and compliance with Class III medical device standards (regulatory compliance).

Hygiene:
This is directly tied to the need for easy cleaning and prevention of microbial contamination (hygiene and maintenance). Connectors must allow safe and hygienic electrode replacement, especially with frequent use.

Stability:
This is linked to the secure fit and durability requirements (design and ergonomics, risk reduction). A stable connection ensures that the electrode remains in place during movement or extended use, which is crucial for consistent therapeutic outcomes.

To evaluate the suitability of each connection mechanism, a qualitative scoring system is applied using the symbols "++", "+", "–", and "– –". These ratings reflect how well each option meets the relevant functional requirements:

++ (Very good):
The option fully satisfies the requirement. It demonstrates high performance, strong reliability, and clear advantages in the given category. This is the most favorable rating.

+ (Good):
The option meets the requirement adequately. Performance is acceptable with minor limitations, but overall functionality remains strong.

– (Poor):
The option falls short of expectations in this category. It has notable weaknesses or limitations that may hinder performance or usability.

– – (Very poor):
The option does not meet the requirement. Significant drawbacks or risks are present, making the solution unsuitable for this application without major modifications.

	Ease of use	Ingress Protection	Safety	Performance/ Connectivity	Hygiene	Stability
Magnetic Pogo Pins	++	++	++	+	++	-
Slide-In Rail System	++	--	++	++	--	++
Pin and sockets	-	--	-	++	--	++
Twist-Lock	-	+	+	+	+	++
Clamp on	-	+	-	+	+	-
Clip-On Connectors	+	+	+	+	+	+

Figure 6-2: Evaluation of connection mechanisms

The connection mechanism plays a crucial role in fulfilling key functional requirements such as safety, usability, hygiene, and ingress protection. Among the evaluated options, the magnetic pogo pin connection is selected as the most suitable mechanism for further development. It achieves the highest overall performance across the evaluation criteria and excels particularly in ingress protection and hygiene, both of which are essential for a reusable medical device designed for rental use.

While the slide-in rail system offers strong mechanical stability and positioning precision, it scores lower on hygiene and resistance to moisture and contamination. These factors are considered critical due to the repeated use and potential exposure to sweat, cleaning fluids, and environmental conditions. The magnetic pogo pin system offers a strong balance between intuitive use, safe electrical connection, and cleanability, making it the most aligned with the functional and clinical demands of the B.stim headset.

This choice ensures reliable and hygienic electrode attachment while preserving ease of use for both patients and professionals. The mechanism will be integrated into the final concept design for further refinement and testing.

6.3. Selection of sizing mechanism

The sizing mechanism plays an essential role in ensuring that the B.stim headset provides a secure, comfortable, and adjustable fit across a wide range of head shapes. A well-designed system supports usability, precision in electrode placement, and long-term wearing comfort. This step directly addresses the How might we question:
“How might we design for different head shapes and electrode configurations?”
By evaluating potential sizing solutions, this phase contributes to meeting both ergonomic and functional requirements essential for adaptability and user satisfaction.

A comparative evaluation is conducted across seven potential sizing mechanisms (Figure 6-3):

- Friction-based adjustments
- Telescoping mechanism
- Dial or screw-based adjustment (e.g., BOA or helmet system)
- Ratchet mechanism 1 (click-based adjustment)
- Magnetic latching adjustment

- Elastic tension adjustment
- Ratchet mechanism 2 (alternative click-based version)

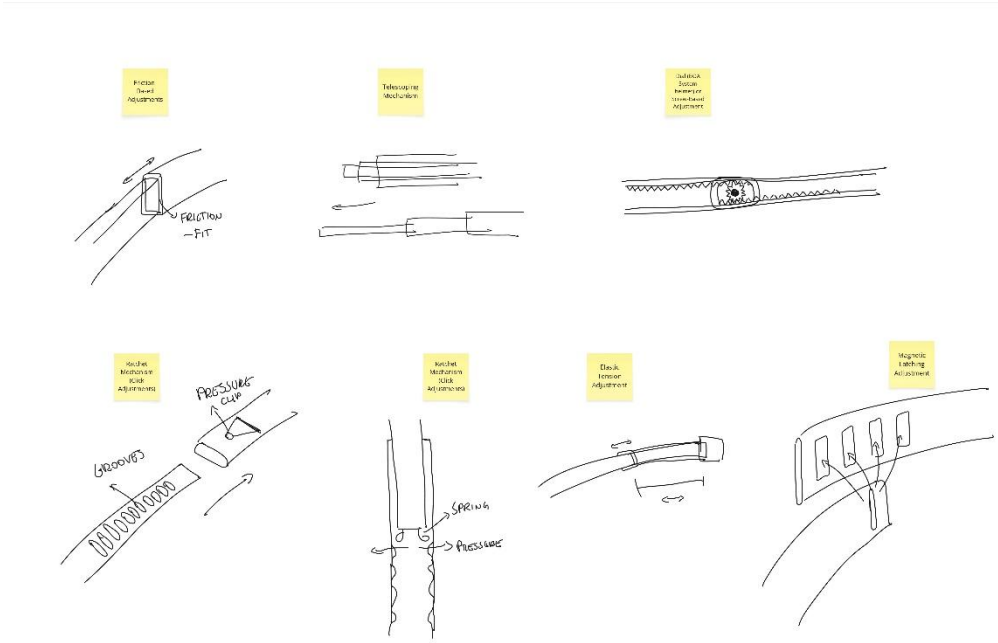

Figure 6-3: concept sketches of sizing mechanisms

Each mechanism is assessed using six key criteria: ease of use, ingress protection, safety, performance/effectivity, hygiene, and stability. The ratings are informed by the functional requirements framework established earlier in the project.

Each rating criterion corresponds directly to defined design and functional needs:

Ease of use:
Supports intuitive sizing adjustment (design and ergonomics), enabling users to easily fit the headset without assistance.

Ingress protection:
Ensures resistance to moisture and contaminants (hygiene and maintenance), essential for reliable and hygienic reuse.

Safety:
Prevents slippage, over-tightening, or discomfort (user safety), and avoids pinch points or skin pressure during long-term use.

Performance / effectivity:
Supports consistent electrode contact and stimulation delivery (performance and functionality), critical to treatment efficacy.

Hygiene:
Reflects ease of cleaning and compatibility with disinfection processes (hygiene and maintenance), especially in a rental use case.

Stability:
Ensures a firm and repeatable fit across different head geometries (design and ergonomics, 2), directly tied to user comfort and electrode accuracy.

To evaluate the suitability of each connection mechanism, the same qualitative scoring system is used as the evaluation of the connection mechanisms. The scores are given with “++”, “+”, “–”, and “– –”. These ratings reflect how well each option meets the relevant functional requirements:

++ (Very good):
The option fully satisfies the requirement. It demonstrates high performance, strong reliability, and clear advantages in the given category. This is the most favorable rating.

+ (Good):
The option meets the requirement adequately. Performance is acceptable with minor limitations, but overall functionality remains strong.

– (Poor):
The option falls short of expectations in this category. It has notable weaknesses or limitations that may hinder performance or usability.

– – (Very poor):
The option does not meet the requirement. Significant drawbacks or risks are present, making the solution unsuitable for this application without major modifications.

	Ease of use	Ingress Protection	Safety	Performance/ Connectivity	Hygiene	Stability
Magnetic Pogo Pins	++	++	++	+	++	-
Slide-In Rail System	++	--	++	++	--	++
Pin and sockets	-	--	-	++	--	++
Twist-Lock	-	+	+	+	+	++
Clamp on	-	+	-	+	+	-
Clip-On Connectors	+	+	+	+	+	+

Figure 6-4: Evaluation of sizing mechanisms

Based on the multi-criteria evaluation of sizing mechanisms (Figure 6-4), the dial-based system (BOA or screw-based adjustment) is identified as the most suitable option for integration into the final B.stim concept. It receives top scores across all functional criteria, including ease of use, safety, performance, hygiene, ingress protection, and stability. This mechanism allows for highly precise and user-friendly adjustments, ensuring a secure and comfortable fit for a wide range of head shapes. Its proven reliability and intuitive operation make it particularly well-suited for medical-grade applications where electrode positioning accuracy and long-term comfort are critical.

The friction-based adjustment system, while slightly behind in overall score, also performs strongly. It ranks second overall, scoring particularly high in ease of use, hygiene, and stability. Its simplicity, low-profile design, and ease of integration into the headset make it a compelling alternative, especially when cost-efficiency or minimal mechanical complexity is prioritized.

Ultimately, the BOA system is selected for implementation due to its superior overall performance and its ability to best meet the ergonomic and usability demands of the B.stim device. It directly addresses the key design challenge of supporting diverse head shapes and electrode configurations, as outlined in the “How might we…” question guiding this phase. The friction-based mechanism remains a valuable fallback or future iteration option due to its structural simplicity and strong baseline performance.

Further refinement of the selected mechanism will follow during CAD development and prototyping, where real-world testing will validate its effectiveness in delivering a comfortable, stable, and customizable user fit.

6.4. Concept sketches of final design

Following the selection of the final concept and the decision to implement a modular electrode system, detailed sketches are created to further define the design direction. The purpose of this step is to visualize how the chosen componentsare integrated into a unified product. These sketches allow for early detection of design conflicts, ergonomic challenges, or component incompatibilities, and they serve as the foundation for the CAD modelling and physical prototyping stages.

6.4.1. Headset

The headset design is based on a dual-band structure connected through a central rotating joint that enables folding from 0° to 180°. This ensures flexibility to accommodate various head shapes and stimulation montages. The bands are contoured to follow the shape of the head, providing ergonomic support and optimal electrode contact.

Key components shown in the sketches include:

- A BOA-based tightening knob, allowing precise and user-friendly size adjustment.
- A series of connection slots distributed along the bands, enabling electrode placement according to the therapy protocol.
- A rotating hinge positioned at the center of the headset, enabling flexible band positioning and compact storage.
- Silicone padding applied to internal surfaces for increased comfort and stability.
- A central electronics module, housing the power source, controller, and communication interface.

This sketch communicates the mechanical layout, sizing mechanism, and product architecture of the various elements, ensuring alignment with previous decisions and functional requirements (Figure 6-5, 6-6).

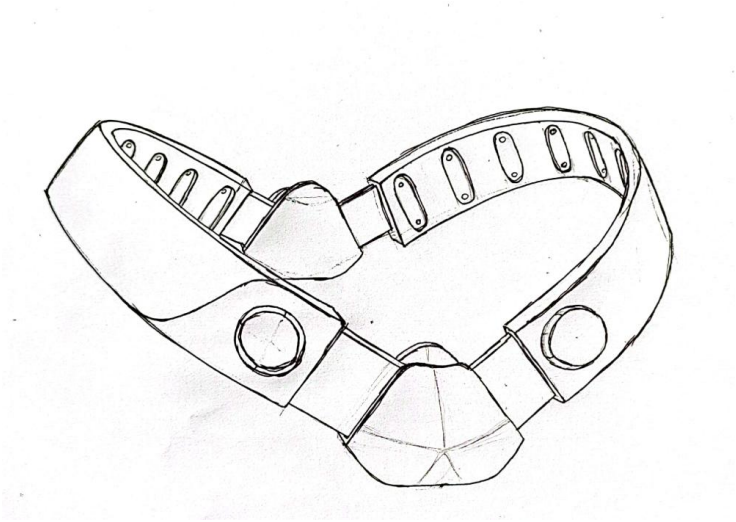

Figure 6-5: Concept sketch of final design

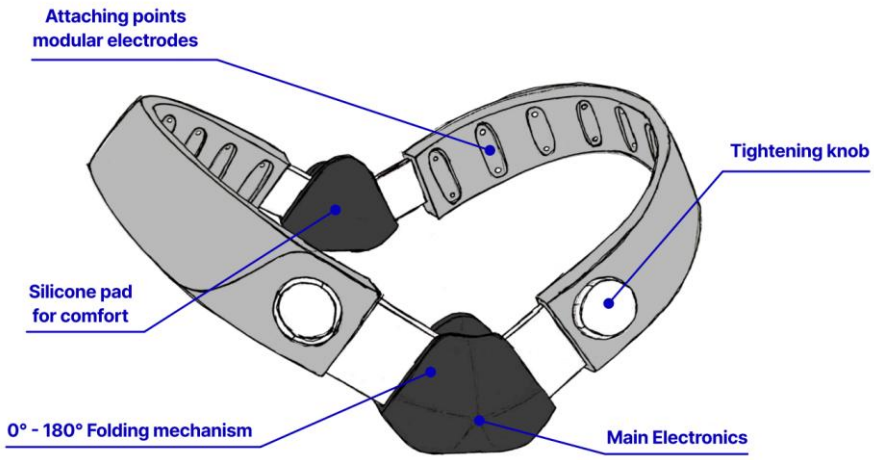

Figure 6-6: Concept sketch with part indications

6.4.2. Electrodes

Separate concept sketches are developed for the modular electrodes, illustrating the adaptability of the connection interface and the variation in electrode configurations. All electrodes are built around a unified connection piece, which ensures compatibility with the headset's mounting system.

three electrode types are developed, each designed to connect to the same universal slot mechanism:

6.4.2.1. Regular Electrode

A compact, sponge-based electrode measuring 4 cm by 5 cm, directly mounted on the standard connection piece. This electrode is intended for general-use TES applications and prioritizes simplicity and reliability. While not included in the sketch visuals, it remains part of the validated electrode family for the B.stim system.

6.4.2.2. Extended Arm Electrode

This electrode consists of a rotatable arm connected to the modular base, with the sponge electrode mounted at the end. It allows the user to extend and angle the electrode beyond the default band surface, offering additional placement flexibility to reach areas that may not align with standard band geometry. The arm's adjustability enhances

configurational precision while preserving modularity. For this electrode, there exist a small medium and large version which correspond to the length of the extention arm. (Figure 6-7, 6-8)

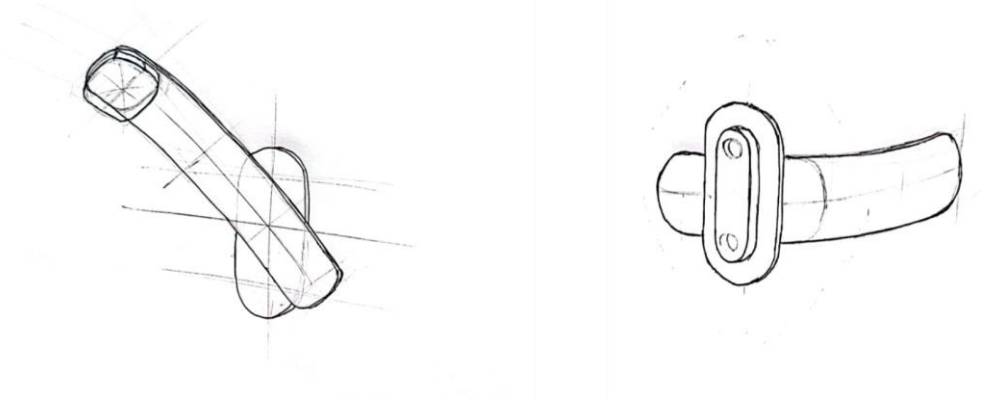

Figure 6-7: Concept sketch of extention arm electrode

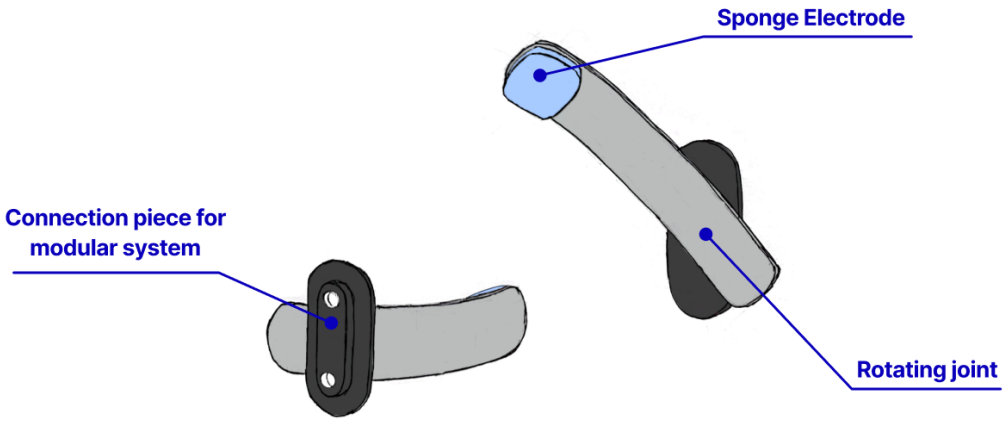

Figure 6-8: Extention arm concept sketch with part indications

6.4.2.3. High-Definition Electrode

A multi-contact design featuring a central negative electrode surrounded by four positive electrodes in a circular arrangement. This configuration is intended for more focused stimulation, such as high-definition TES protocols. It uses the same modular base and is interchangeable with other electrode types, ensuring compatibility across stimulation setups. (Figure 6-9, 6-10)

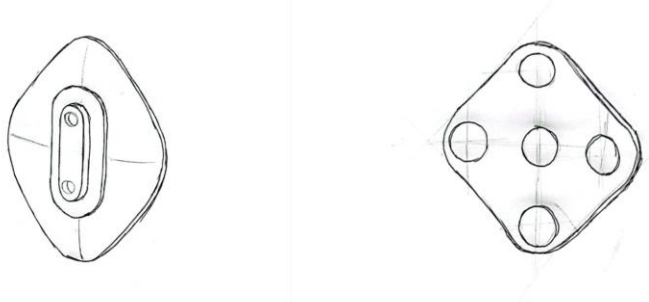

Figure 6-9: Concept sketch of high definition electrode

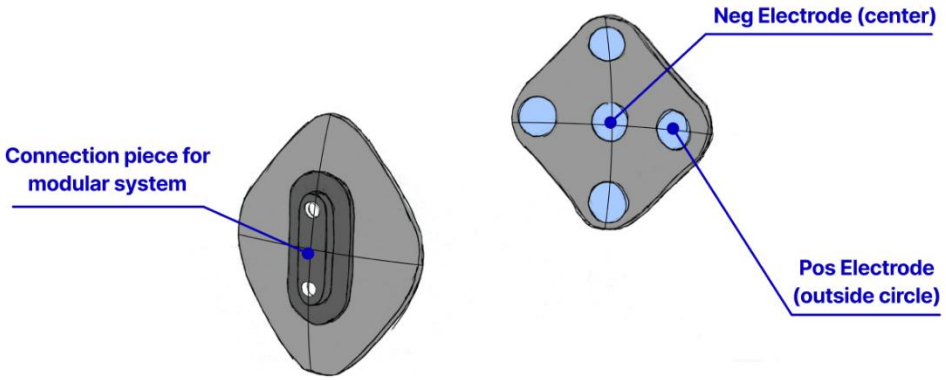

Figure 6-10: High definition electrode concept sketch with part indications

All electrode types make use of the same connection interface, ensuring ease of swapping, cleaning, and positioning without requiring mechanical changes to the headset. This modularity enables both clinicians and users to select the most appropriate electrode for a given treatment while preserving system consistency.

The concept sketches visually consolidate all major elements of the B.stim headset, from its adjustable dual-band structure to the modular electrode system. By including three electrode types—regular, extended arm, and high-definition—the design supports a broad range of stimulation montages and therapeutic scenarios. The modular architecture ensures user configurability, ease of use, and clinical adaptability. These sketches provide the foundation for technical detailing in the next phase, including CAD modelling and prototype construction, where ergonomics, tolerances, and assembly logistics will be further explored and validated.

6.5. Viscom phase II

To further develop the visual definition of the B.stim concept before entering the CAD modelling phase, a second round of visualization is performed using the Viscom platform. This is an AI-based tool that generates photorealistic renderings from sketches and descriptive prompts. This step serves as an intermediate design aid, providing a more realistic impression of the final product's form, proportions, and surface qualities. The objective is to evaluate the spatial and aesthetic aspects of the design in greater detail, and to guide decisions on component definition and layout before technical modelling begins.

The final concept sketches of the headset and modular electrodes are uploaded to the Viscom image generation platform. Descriptive prompts are added to guide the rendering engine in interpreting material choices, context, lighting, and form. The output includes a series of photorealistic images that visualize the geometry and of the headset in multiple styles and surface material suggestions, including matte plastic, silicone, and anodized finishes (Figure 6-11). These images do not represent technical accuracy but provide visually rich, high-fidelity representations of the intended product. They support reflection on design details such as proportions, component integration, visual hierarchy, and ergonomic perception.

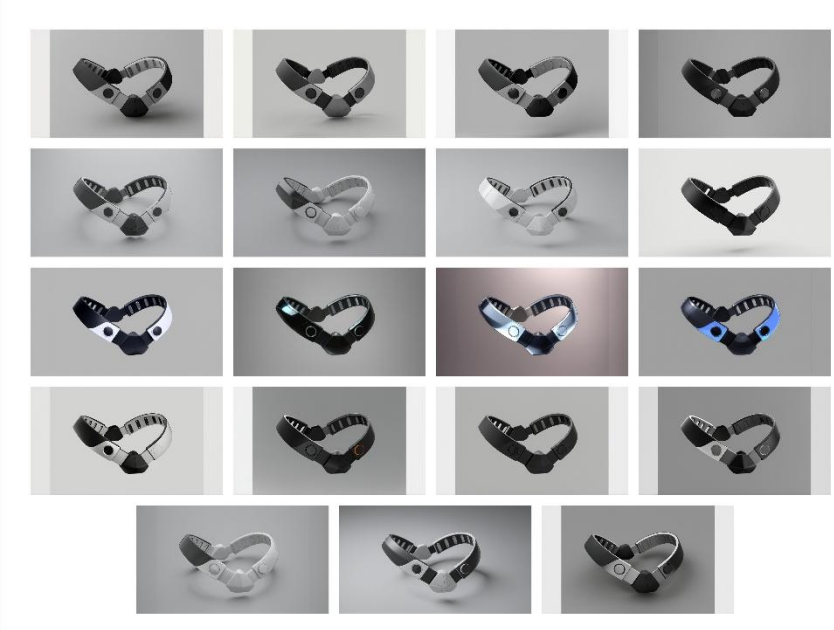

Figure 6-11: Viscom ideation images of headset

The Viscom phase II renders offer a valuable visualization step between sketching and CAD modelling, allowing for intuitive evaluation of design features in a realistic context. This process aids in identifying different parts for production, placement, and styling before formalizing the geometry in a 3D environment.

6.6. Cad design I

Before proceeding to the full CAD development of the B.stim headset, a preliminary evaluation is conducted to test the feasibility of the modular electrode connection system. The aim of this step is to assess whether a basic male-to-female connector design can provide a reliable mechanical and electrical interface for interchangeable electrode modules. Given that the modular system is central to the adaptability and usability of the final product, validating this connection concept early is essential.

6.6.1. Modular electrode prototype

A simplified 3D model of the connector interface is created and printed using a 3D printer. The test focuses exclusively on the mechanical fit between the male connector (attached to the electrode module) and the female port (integrated into the headset structure). No electronics are included at this stage; the purpose is to evaluate tolerances, insertion force, stability, and removability. Magnets are used in the connection system to prevent incorrect orientation of the electrode during attachment. This is achieved by reversing the polarity of the top and bottom magnets in each connector, ensuring that the electrode can only be inserted in the correct position. To test the effectiveness of this approach, magnets are manually inserted into the designated cavities of the 3D-printed parts.

The design mimics the intended geometry for the final modular system, including alignment features and snap-fit or friction-based retention mechanisms. The print is produced at 1:1 scale and manually tested for repetitive insertion and removal (Figure 6-12).

Figure 6-12: Electrode connector prototype

Figure 6-13: Electrode connector evaluation

The connector evaluation confirms the mechanical feasibility of the modular male-to-female interface for electrode attachment (Figure 6-13). The printed components demonstrate good stability and ease of use, validating the fundamental geometry of the connection system. To further improve user guidance and prevent incorrect orientation, magnets with reversed polarity are incorporated into the top and bottom of each connector. This magnetic alignment system ensures that electrodes can only be attached in the correct position. Initial tests, using manually inserted magnets in the 3D-printed prototypes, show promising results in both alignment accuracy and connection consistency. These insights support the continued development of the modular electrode system and guide the refinement of connector geometry in the subsequent CAD modelling phase.

6.6.2. Cad model

The first CAD model is developed to obtain a realistic impression of the B.stim headset's physical dimensions, part integration, and mechanical layout. This model serves as a technical translation of the final concept sketches and a starting point for iterative refinement. It is not yet intended to be production-ready but functions as a test platform to validate fit, assembly, and proportion through both digital inspection and physical prototyping.

The CAD model is constructed based on the visual and functional outcomes of the previous phases. It includes the following key components (Figure 6-14):

Headband:
Shaped to follow the contours of the human head, and fitted with female-type electrode connector ports along its inner surface.

Fit adjustment knob:
A representation of the selected rotating dial tightening mechanism, placed on the outer side of the band.

Extension arm:

This part is the connection between the central module and the headband of the headset. It allows the headset to be folded open and closed and also to extend or shorten the headbands length

Central module:
Positioned at the joint between the headband arms, this module houses the main electronics, including the battery and controller and also served as the hinge that allows the headset to fold from 0 tot 180 degrees.

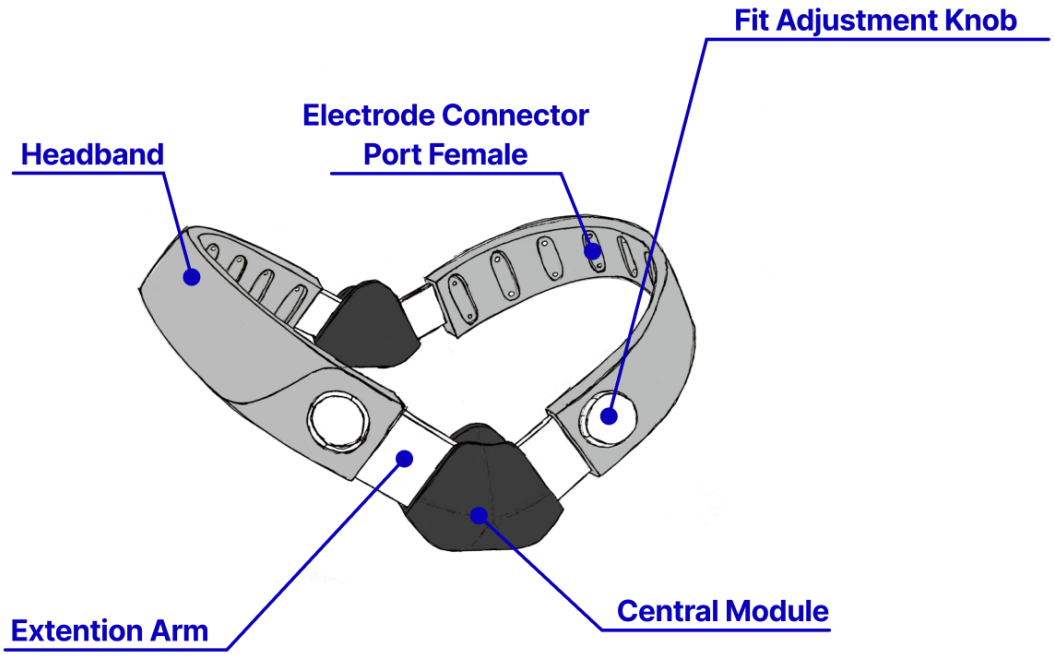

Figure 6-14: Key components of CAD model

To define the correct anatomical proportions of the headset (Figure 6-15), anthropometric reference data is applied from a study by the University of Antwerp on the evaluation of a shape model of the human scalp [27]. This provides a data-driven foundation for headband curvature, length, and sizing assumptions.
In addition, a preliminary internal layout is explored, in which the locations of the main electronics, the wiring routes, and the sizing mechanism are indicated. This spatial analysis informs upcoming iterations and prepares the model for integration of technical components.

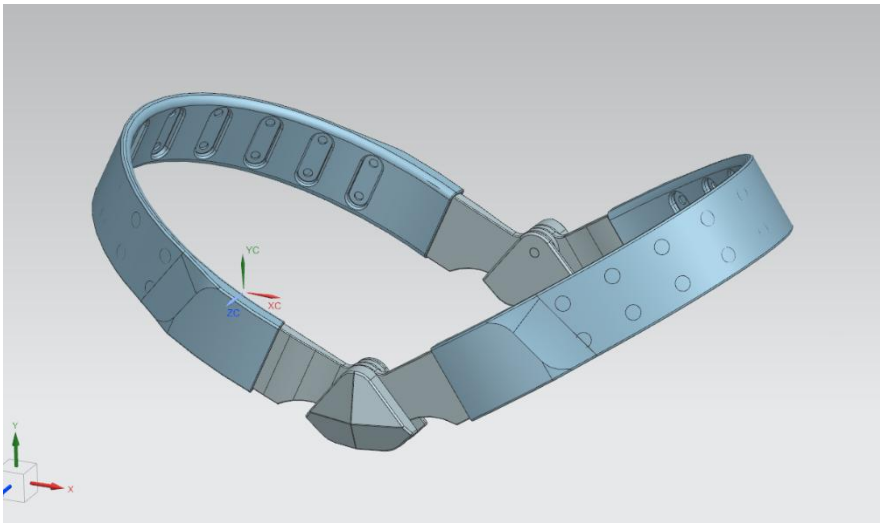

Figure 6-15: First CAD model

6.6.3. 3D prints

To assess the physical dimensions and ergonomic fit of the design, the CAD model is translated into a 3D-printed prototype (Figure 6-16). The parts are printed in scale to verify curvature, contact zones, component interaction, and wearability. This prototype allows for a quick and tangible evaluation of how the headset fits on the head, how the adjustment knob aligns with the hands, and how much room is available in the central module for electronic integration. The parts are printed on a Prusa MK3 printer using PLA filament.

Figure 6-16: 3D-printed parts

6.6.4. Validation of design

The printed prototype reveals a key issue in the dimensional assumptions: an error in the sizing calculation results in a headset that is slightly too large. This deviation, although minor, highlights the importance of physical validation even in early design phases. Despite the sizing discrepancy, the 3D print provides valuable insights into the spatial layout, visual proportions, and mechanical logic of the design.

This evaluation informs the next iteration of the CAD model, where adjustments will be made to improve anatomical accuracy, refine fit, and continue toward functional prototyping.

6.7. Cad design II

6.7.1. Cad model

Building upon the insights gained from the initial CAD modelling phase, a second version of the B.stim headset is developed to refine the design and improve various parts (Figure 6-17). This step aims to implement design modifications, especially concerning the sizing mechanism and internal routing for electronics, while preparing the headset structure for manufacturability. As in the previous phase, the process includes modelling, 3D printing, and evaluation of the physical prototype.

In this iteration, the BOA-style adjustment system is replaced with a friction-based sizing mechanism. Although the BOA system scored highest in the earlier evaluation, the friction-based system is selected for integration due to its simpler geometry and the additional internal space it allows for routing electronic components through the headband. The selected system also performed comparably in the sizing mechanism evaluation and better supports the minimalist, modular design approach of the B.stim headset.

Key developments in this CAD model include:

- Redesigned headband, shaped to fit the human head based on anthropometric data, and optimized to allow the future use of a flexible material. While the current version is made from non-flexible material, the final version is intended to provide light pressure through elasticity, improving comfort and electrode contact. (Figure 6-18)

- Updated central module, adjusted for easy assembly and improved internal volume to accommodate electronics such as the microcontroller, battery, and connectors. (Figure 6-19)

The model is built with manufacturability in mind, using part separation and wall thicknesses that are suitable for future production techniques beyond prototyping.

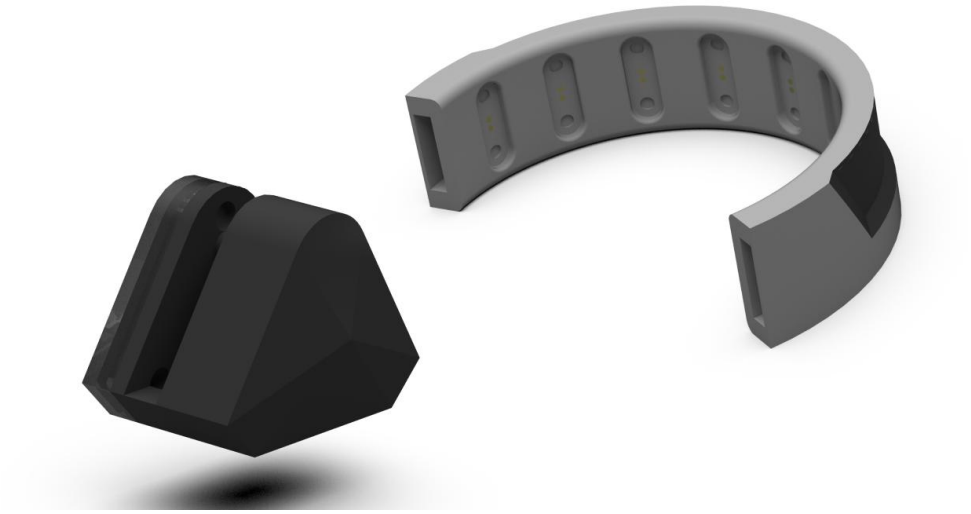

Figure 6-17: Updated headband and central module

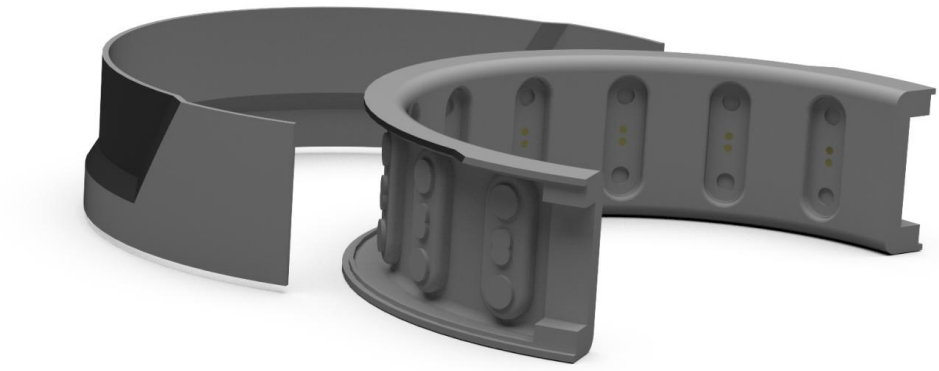

Figure 6-18: Updated headband

Figure 6-19: Updated Central module

6.7.2. 3D prints

The complete model is printed using standard PLA, which provides sufficient rigidity to evaluate mechanical fit and spatial layout. Although PLA does not reflect the elastic properties planned for the final headband material, it allows for testing part geometry, connection points, and ergonomic alignment. (Figure 6-20)

All components are printed to full scale, including the updated headband, central module, and integrated friction adjustment features. The print enables a hands-on review of how components align and whether sufficient space is provided for planned internal electronics.

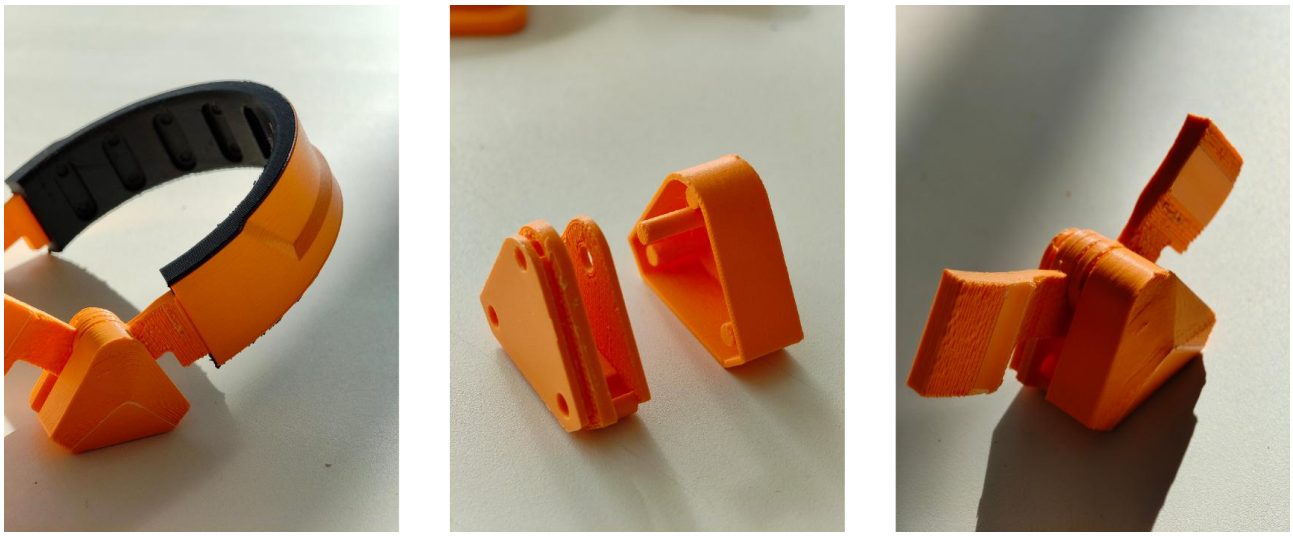

Figure 6-20: 3D printed prototype

6.7.3. Validation of prints

The evaluation of the second 3D-printed prototype provides several important insights for further refinement. One key issue identified is the hinge section of the central module, which is found to be too narrow to feasibly allow internal routing of electronic components. Although the overall central module offers improved volume, the limited space within the hinge region poses a constraint for cable passage and must be redesigned in future iterations to ensure both mechanical strength and functional integration.

In contrast, the assembly connection between components designed for production fit together precisely in the printed prototype. This validates the dimensional assumptions used in the CAD model and confirms the design's suitability for future production methods.

Overall, the prototype confirms the general fit and form of the headset structure, while also identifying critical areas for improvement related to internal component routing and hinge redesign. These findings directly inform the next phase of development, which will focus on fitting of electronics in the design.

Develop phase II successfully confirms the feasibility of modular electrode integration and validates the key mechanical systems needed for user-specific adaptation. It finalizes the physical configuration for the next phase of functional integration. Although the BOA system performs well in theory, the chosen friction-based solution better supports electrical routing, demonstrating an informed design trade-off.

7 Develop Phase III

The third development phase focuses on the user experience, electronics integration and refinement of the B.stim headset. While earlier phases addressed form, mechanical components, and modularity, this phase introduces the internal electronic architecture, materials and finishes, and the user interaction flow. This ensures that the product moves toward a viable, safe, and user-friendly medical device.

7.1. Electronic component selection and schematic

To initiate the integration of electronics into the headset, first a component selection needs to be conducted. This includes identifying a microcontroller, power supply, current control system, switching components, and other safety-critical electronics. The selection process is guided by benchmarking existing TES devices and reviewing technical documentation and online articles to ensure clinical appropriateness, safety compliance, and compactness.

To determine the feasibility of integrating electronics into the B.stim headset, a preliminary system schematic is created. This schematic includes all major electrical components required to power, control, and safely deliver transcranial electrical stimulation (TES). The schematic provides a foundational overview of component interaction and supports early-stage spatial and functional planning.

7.1.1. Component Overview and Functions

Battery (3.7V Li-Po):
The primary power source for the headset. It supplies direct current to all electronic components and must be compact, rechargeable, and medically safe. The 3.7V rating is widely used in other benchmarks.

LP5907 voltage regulator:

A low-dropout voltage regulator that regulates the voltage coming from the battery to a stable and safe level suitable for the microcontroller.

Seeed XIAO ESP32C3 (microcontroller):
This microcontroller is responsible for the main processing tasks. It includes Bluetooth and Wi-Fi capabilities, allowing the device to communicate with an external interface (a mobile app). It controls stimulation parameters.

DAC43508 (Digital-to-Analog Converter):
Converts the microcontroller's digital stimulation commands into analog signals. This enables control over stimulation waveform, amplitude, and duration.

OPA2140 Operational Amplifier
Used for filtering and amplifying the output signal before delivery to the electrodes. Ensures the signal is smooth and within the desired voltage range.

LT3092 current source
Provides a constant current output, which is essential for safe and consistent TES delivery. It ensures that current levels remain stable regardless of fluctuations in electrode impedance.

TMUX6112 analog switch
Functions as a multiplexer to enable electrode switching. It allows the system to route stimulation current to different electrodes based on user configuration or protocol requirements.

Bourns HCT (galvanic isolation)
Provides electrical isolation between the user and the rest of the electronic system. This is critical for patient safety, preventing unwanted current from entering the user's body in case of electrical faults.

Flexible PCB (30cm x 3cm, with a thinner end part)
A flexible printed circuit board allows for routing of signals and power between components in the headset's limited and curved internal space. It connects the main electronics to the female electrode connector ports.

Pogo Pins (BCE electronics, current rating: 3 Amps, Diameter: 1.45, length 3mm)
These spring-loaded connectors are used to create modular, removable connections between the electrodes and the headset. They allow easy electrode replacement and reconfiguration while maintaining a reliable electrical contact. Because they are spring loaded, they keep good contact between the male and female connector ports even when they are not optimally connected.

Slip Ring (rotarX, RX-Min13D 6 rings 2A)
Allows continuous electrical connection across rotating parts, such as the rotating extention arm of the modular electrodes. This makes it possible to transmit signals and power across the adjustable sections of the device without interrupting the circuit.

Electrodes (sponstim neuroelectrics, snappad soterixmedical, custom made)
Electrodes that deliver the electrical stimulation to the scalp. These are connected to the end of the extention arm and receive current from the male electrode connector port trough the housing of the modular electrodes. They are connected with a snap fit and can be removed for rinsing.

App Interface

Represents the external software environment, used to control stimulation parameters, track session data, and guide the user through setup and use.

Power Button (Mouser 179-TS32735B260RASMT)
Used to activate or deactivate the device manually.

Status LEDs (Diorama 1206 Cool-White SMD LED)
Provide visual feedback on device status (e.g., power on, stimulation active, Bluetooth connected), supporting user awareness and safety.

7.1.2. Battery selection

To determine the most appropriate battery for integration into the B.stim headset, a power consumption analysis is conducted. This involves evaluating the current draw of each selected component and estimating the total energy demand during a standard stimulation session. (Figure 7-1)

The analysis begins by identifying the average current consumption of key components, including the microcontroller, DAC, amplifier, current source, TMUX, the stimulated current, and other losses. Based on the combined current requirements, the total power usage for a typical 30-minute session is calculated.

Component	Current Draw (Typical)	Notes
Seeed XIAO ESP32C3	<75 mA (with WiFi/Bluetooth)	WiFi draws bursts, but assume peak use
OPA2140 op-amp	~1.8 mA (max)	Low power analog stage
LT3092 current source	~2 mA + user output	Output to user ~2 mA
TMUX6112	/	/
Bourns HCT isolator	/	/
DAC43508	3mA	at normal mode
Other losses	~10 mA estimated	Includes regulators, switching losses, etc
Stimulated Current	~2mA	
Total estimated	~100	

Figure 7-1: Power concumption analysis

Based on the combined power demands of the selected electronic components, an average current draw of approximately 100 mA is assumed.

Using the formula:
Battery capacity (mAh) = Current draw (mA) × Time (h)

The estimated energy consumption for one session is:
100 mA × 0.5 h = 50 mAh

To account for energy losses, inefficiencies, and power consumed by system overhead (such as indicator LEDs, standby functions, or wireless transmission), a safety margin of 20% is applied:

50 mAh × 1.2 ≈ 60 mAh per session

This value is then used as the baseline for comparing battery options and estimating how many full sessions a given battery can support on a single charge. The battery selected for integration must therefore deliver at least 60 mAh per session while fitting within the spatial constraints of the headset's central module. (Figure 7-2)

Model	Capacity (mAh)	Sessions (est.)	Dimensions (mm)	Thickness	Weight (g)
301230	100 mAh	~1.5 sessions	30 × 12 × 3.0	3.0 mm	~2 g
401230	130 mAh	~2.2 sessions	40 × 12 × 3.0	3.0 mm	~2.5 g
301525	150 mAh	~2.5 sessions	30 × 15 × 2.5	2.5 mm	~3 g
401220	120 mAh	~2.0 sessions	40 × 12 × 2.0	2.0 mm	~2.5 g
302025	180 mAh	~3.0 sessions	30 × 20 × 2.5	2.5 mm	~3.5 g
502030	250 mAh	~4 sessions	50 × 20 × 3.0	3.0 mm	~5 g
401730	200 mAh	~3.3 sessions	40 × 17 × 3.0	3.0 mm	~4 g

Figure 7-2: Battery comparison

With this estimation, various battery options are compared according to the number of full stimulation sessions they could support on a single charge. Additionally, the physical dimensions of each battery are reviewed, with particular focus on thickness, to ensure compatibility with the constrained internal volume of the CAD model.

Following this comparison, battery 401220 for its very thin form factor and capacity for 2 full sessions. This ensures that the battery can be realistically integrated into the central module of the headset without compromising ergonomics or aesthetics, while still meeting user expectations for daily or repeated use.

7.1.3. Schematic

After identifying and describing the key electronic components required for the B.stim headset, all elements are brought together in a basic schematic. This schematic provides a functional and spatial overview of where each electronic component will be placed within the overall design. The aim is not to present a final circuit diagram but to give a clear representation of how the system is architecturally organized across the different physical zones of the device—namely the central module, headband, and extention arms. (Figure 7-3)

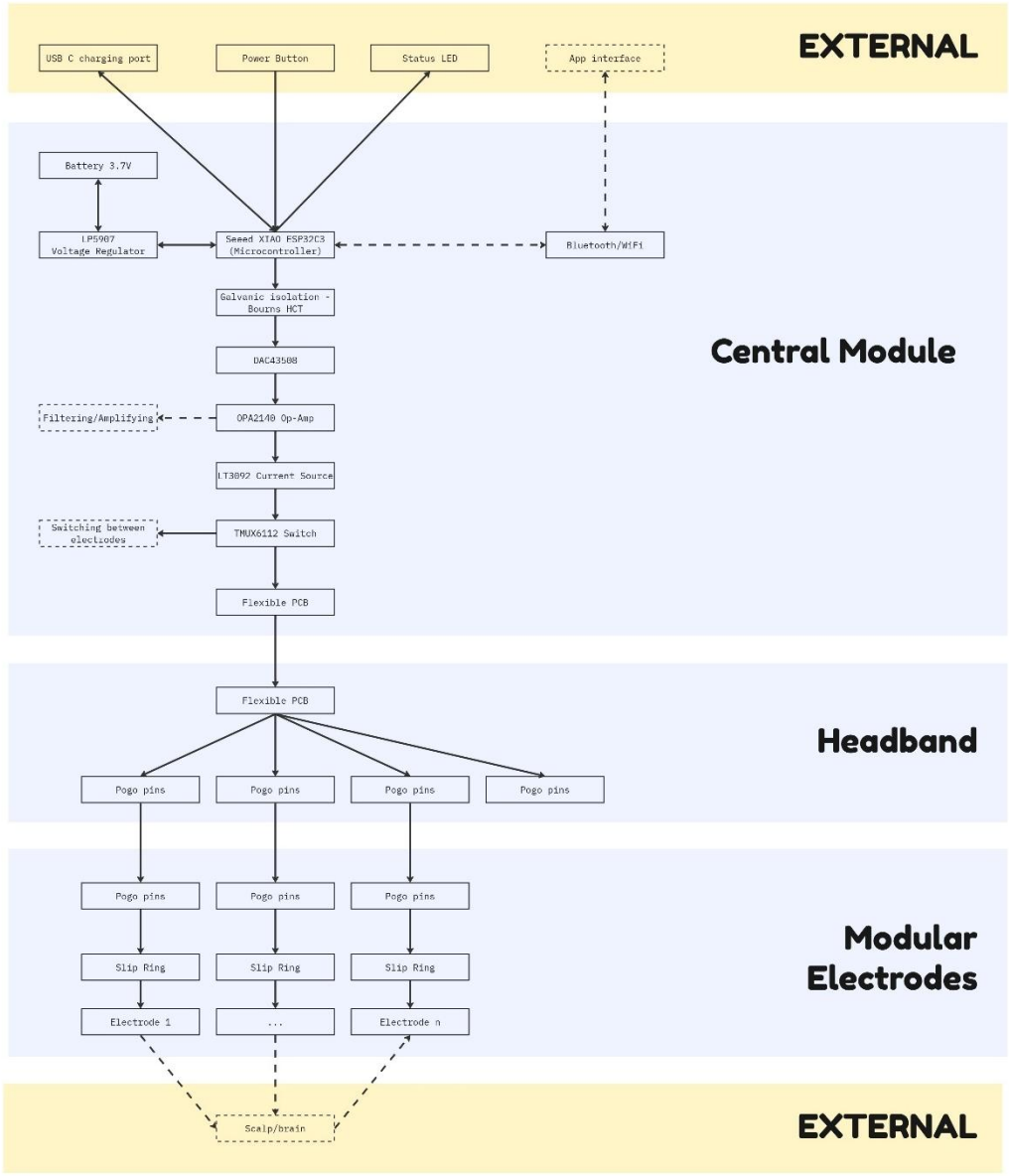

Figure 7-3: Basic electronics schematic

To demonstrate how the system would operate under real usage scenarios, two example stimulation configurations are included in the schematic:

7.1.3.1. Standard Stimulation

This example reflects a typical two-electrode configuration, using a cathode and anode placed on opposite ends of the headband or modular arms. It shows how the stimulation current from the TMUX switch trough the flexible electrode to the selected electrode connector ports. In these connector ports, both the pogo pin connectors are of the same polarity and they connect to the electrode. (Figure 7-4)

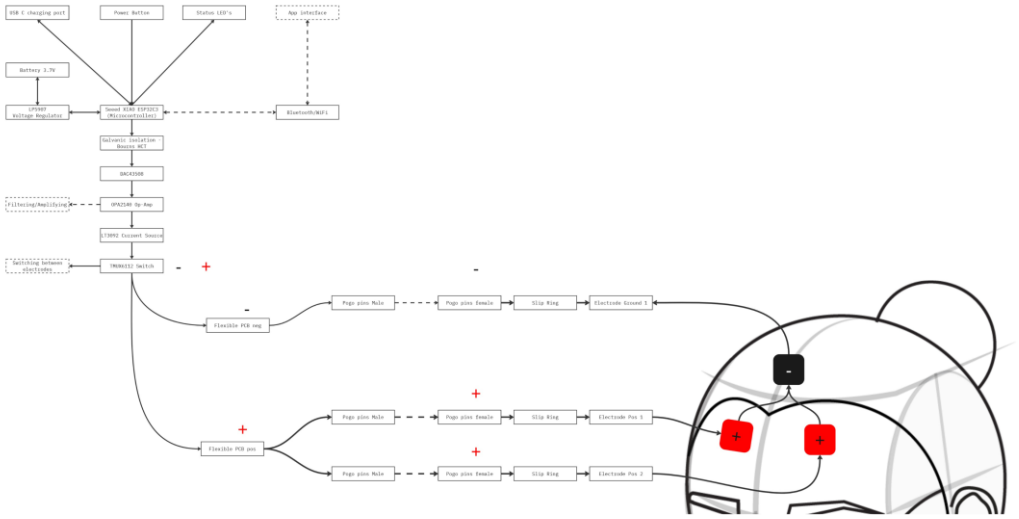

Figure 7-4: Standard stimulation schematic

7.1.3.2. High-Definition (HD) Stimulation

This second example illustrates a high-definition montage, where a central cathode is surrounded by four anodes to create a focused stimulation field. The schematic shows how the current goes from the TMUX switch to the flexible pcb and to the single electrode connector port for the high-definition electrode. There positive and negative current each go through a respective pogo pin connection, which then goes to the electrode. (Figure 7-5)

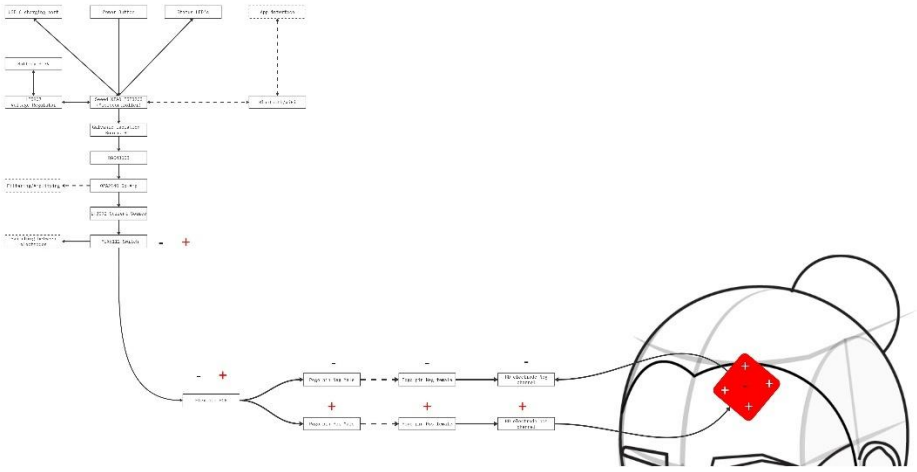

Figure 7-5: High-Definition schematic

These example configurations help validate the versatility of the schematic and confirm that the current component selection supports both standard and advanced stimulation protocols. This schematic also serves as a guiding reference for the subsequent CAD rework, which focuses on integrating these electronics spatially within the headset design.

7.1.4. Electrode impedance monitoring

To enhance safety during transcranial electrical stimulation, an electrode impedance monitoring mechanism was integrated into the existing circuit. This system ensures that stimulation is only delivered when proper electrode-skin contact is established, reducing the risk of ineffective treatment or adverse skin effects.

The existing precision operational amplifier (OPA2140) is repurposed in a differential amplifier configuration to measure the voltage drop across the stimulation electrodes. A low test current is briefly injected through a precision resistor (10 kΩ) during predefined pauses in the stimulation. This injection path is activated via the existing analog switch (TMUX6112), which toggles between stimulation mode and measurement mode.

During the measurement phase, the test current is applied across the electrodes. The OPA2140 amplifies the differential voltage, which is then sampled by the microcontroller's ADC (XIAO ESP32C3). Using Ohm's law, the system calculates the electrode impedance. If the measured impedance exceeds a defined safety threshold, stimulation is automatically halted, and the user is prompted to adjust the electrode placement or apply more saline solution to the electrodes.

This integration of impedance monitoring using existing components enables real-time safety checks without significantly increasing circuit complexity or component count.

7.2. Cad rework for electronic integration

Following the creation of the basic schematic and the selection of electronic components, the CAD model of the B.stim headset is reworked to support the spatial integration of electronics. This phase focuses on adapting the mechanical design of the headset to accommodate the selected components, improve internal routing, and prepare the structure for future PCB placement and assembly. It ensures that the final design can physically house all functional parts without compromising usability or form factor.

7.2.1. Model

The central module is the primary area of focus in this rework. Originally consisting of three parts, the structure is simplified to just two components, reducing complexity and creating a more efficient interior layout. This reconfiguration also enables easier wire routing from the central module through the hinges and into the headband.

In addition to the simplified layout, the internal volume of the central module is increased. This adjustment ensures that more space is available to accommodate key components such as the microcontroller, DAC, current source, and galvanic isolation modules. (Figure 7-6, 7-7)

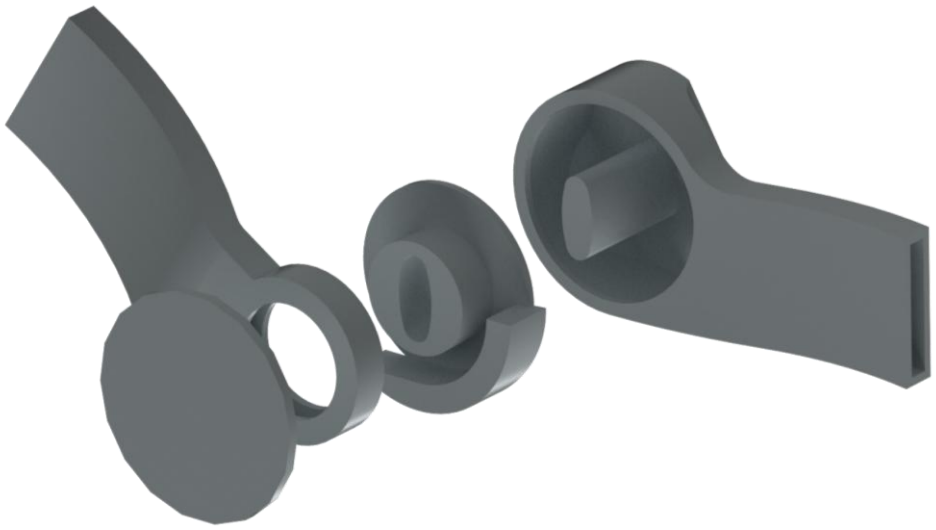

Figure 7-6: Exploded view of reworked central module

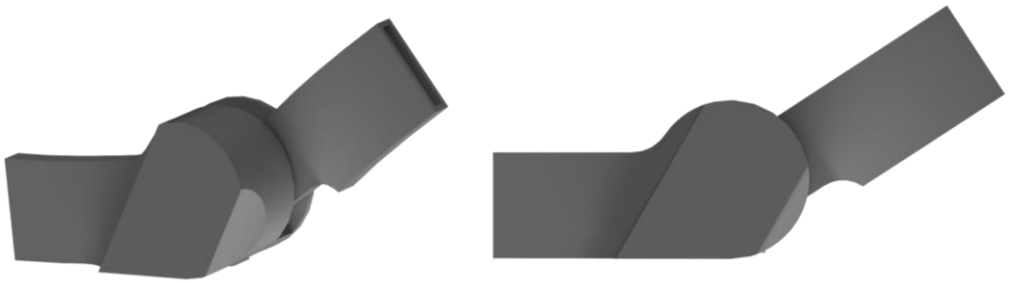

Figure 7-7: Reworked central module

7.2.2. Placement of components

To assess the spatial feasibility of integrating the electronics, representative CAD models of all major components are created based on technical documentation and datasheet dimensions. These models are placed within the updated central module to evaluate whether each component fits within the available volume. (Figure 7-8)

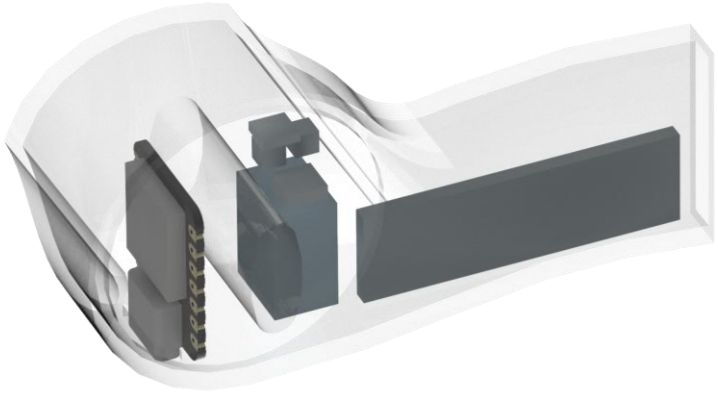

Figure 7-8: Placement of components

This analysis confirms that the new module geometry is sufficient to house the full system, and informs the prioritization of component placement zones for thermal, accessibility, and connectivity considerations.

7.2.3. Power button and LED

As part of the integration, the power button is placed on the central module (Figure 7-9). It is positioned on the edge of the outward positioned surface of the central module. This position is easy accessible for the user and on the opposite side of the head so the button won't be pressed by the ear or head when the headset is worn. The location ensures clear tactile feedback without interfering with other design elements. The button turns the device on and off when it is long pressed for 2 seconds. This prevents the headset from turning of after an accidental tap. The same mechanism is often used in headphones.

Additionally, the status LED is placed above the power button which so that it is visible when powering the device on and from most other viewing angles of the device. The LED location is selected to be easily visible during setup,

supporting safety and ease of interaction. When worn the LED won't be visible to give visible peace, the status indication is not needed in this stage because the patient can see everything on the app. This LED provides feedback on device status, such as power on, stimulation active, or Bluetooth pairing. The led indicates the following device statuses:

- None: device is powered off
- Blinking: device is turned on and searching for a Bluetooth connection
- Solid: device is powered on and Bluetooth is successfully connected
- Pulsing (wave-like brightness fluctuations): electrical stimulation is active

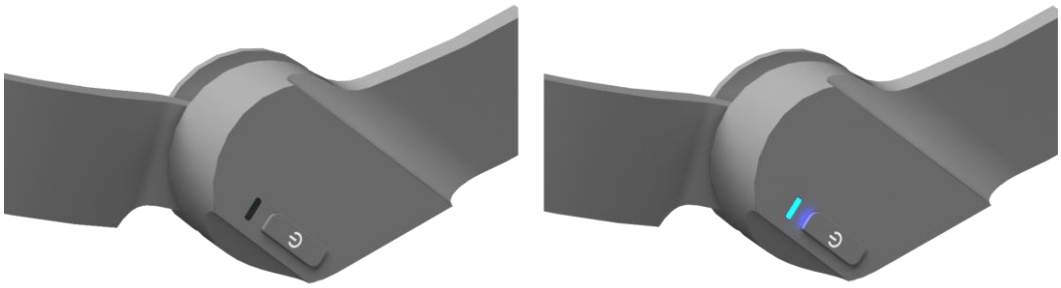

Figure 7-9: Powerbutton and status-LED

The integration of the power button and status LED into the central module enhances both the functionality and user experience of the B.stim headset. Their placement is carefully considered to ensure intuitive access, reduce the risk of accidental activation, and provide clear, non-intrusive feedback. By adopting familiar interaction patterns and limiting visual distractions during use, the interface design supports a calm and user-friendly stimulation experience. Another example of this is the long press for power control. These elements contribute to the overall usability, safety, and visual coherence of the device, reinforcing its suitability for both home and clinical settings.

7.3. Colors, materials and finishes (CMF)

The visual and tactile qualities of the headset are defined through a CMF study. This includes selecting colors, materials, and surface finishes that reflect both the functional needs and desired identity of the device. The process is based on the following elements:

- The Functional Requirements Document, which specifies material properties such as hygiene, cleanability, and skin contact safety.
- Benchmarking of comparable medical devices, to identify standard practices for medical aesthetics and user trust.
- User interviews, conducted to gather preferences regarding the look and feel of the headset in terms of material finish and color choices.

Two moodboards are created, one for colors and one for material and finishes, to consolidate findings and guide further design (Figure 7-10, 7-11). The selected materials aim to balance softness, professionalism, and product recognizability, while also supporting ease of cleaning and medical-grade compliance.

Figure 7-10: Moodboard color

Figure 7-11: Moodboard materials and finishes

A detailed material and finish selection was developed for each component of the B.Stim headset. This selection process aligns with the functional and emotional criteria defined during earlier project phases, particularly hygiene, user comfort, and device durability. Each material was chosen based on its compatibility with prolonged skin contact,

cleanability, waterproofing, weight, and its role in promoting a relaxed and non-clinical user experience. The following section outlines the key choices and their justifications.

7.3.1. Headband – Outer component

The headband is constructed using a dual-material strategy. The outer structural band is made of medical-grade PC/ABS, a plastic blend offering high impact resistance and dimensional stability. This material is commonly used in medical enclosures for its strength, chemical resistance, and ability to withstand frequent cleaning. This also serves as the core of the headband which will apply pressure by keeping the headband in curved shape.

The inner surface of the headband, which comes into direct contact with the user's skin, is made out of polypropylene. This material is chosen because of its good fatigue resistance, it is chemically inert and it is lightweight.

7.3.2. Electrode Casings

All electrode casings are produced in PC/ABS plastic, ensuring mechanical durability and water resistance, particularly important since the sponge electrodes may be moistened during use. The electrode edges may be overmolded with silicone rims to soften skin contact zones. The external surface features a satin or matte finish to avoid glare and to ensure cleanability, while retaining a professional aesthetic.

Colorwise, the electrodes follow the device's unified palette to avoid a medical or technical appearance. Functional color accents (e.g. for polarity) are introduced in muted tones.

7.3.3. Central Module – Electronics Enclosure and Extension Slider

The central module and extention slider are also made from PC/ABS. This casing is coated internally with a thin conductive metal layer (via electroless plating or conductive paint) to provide EMI shielding that protects the headset's sensitive stimulation and communication components. This shielding approach is often done in wearables and medical devices, to meet both safety and regulatory expectations. The outer surface remains consistent with the headband's matte finish and neutral color scheme. Seam design allows for waterproofing via silicone gaskets at critical joints, allowing wipe-down or occasional rinsing.

7.3.4. Removable Cushioning Pad

The cushioning on both sides that supports the central module against the sides of the head is made from soft silicone gel or foamed silicone, offering excellent pressure distribution and user comfort. It is covered in a skin-safe, matte-finished surface that avoids tackiness and supports airflow. This pad is designed to be easily removable and washable, satisfying hygiene needs.

7.4. User Experience

To ensure a smooth and intuitive therapy process, the user experience (UX) is defined and visualized. This UX journey outlines the steps a user would follow during a stimulation session and identifies key touchpoints, feedback moments,

and potential user concerns. The format is based on the service blueprint schematic used in earlier phases but adjusted to focus on the interaction between the user, the device and the mobile application.

The key stages in the UX journey include:

- Introduction: a one-time onboarding step that occurs only during the user's first interaction with the device
- Pre-session: preparatory actions carried out prior to stimulation
- Initiation: the immediate steps leading up to the start of the stimulation session
- During stimulation: the active stimulation period
- End of session: the conclusion of the stimulation process
- Post-session: final actions to wrap up the session

7.4.1. Introduction

The user experience begins with a guided walkthrough of a full stimulation session, conducted under the supervision of a medical professional. This introductory session is designed to ensure that the user becomes familiar with the device, app, and overall procedure in a safe and supported environment. The medical professional assists the user in setting up the device, explains the correct electrode placement, and demonstrates the session flow while offering clarification on important safety and comfort aspects. This phase builds user confidence, reduces anxiety associated with first-time use, and establishes correct usage habits for future independent sessions. (Figure 7-12)

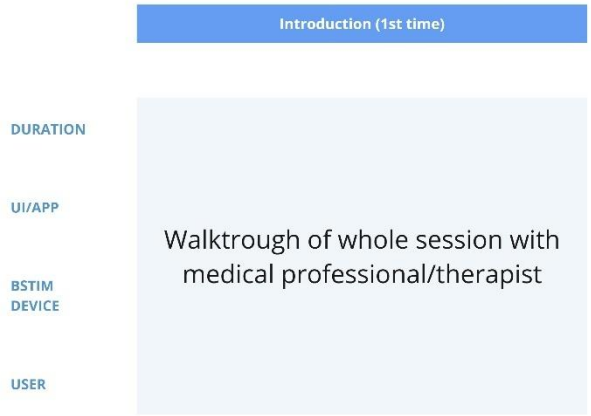

Figure 7-12: Introduction

7.4.2. Pre-session

The session begins with an automated notification from the app, reminding the user to start their session at the time they selected. Once the app is opened, setup instructions are presented to guide the user. The user is prompted to power on the device, which simultaneously initiates the Bluetooth pairing. Once the connection is established, the app checks the battery level to ensure it is sufficient for the full session. If the battery is too low, the user is prompted to charge the device and return later. If the battery level has been checked, the app shows which electrodes are needed. The user is instructed to prepare the electrodes by submerging the sponges in a saline bath, and then to follow visual and audio cues to place them on the correct positions. An audible beep from the app and visual confirmation from the app are used to validate correct placement. (Figure 7-13)

Figure 7-13: Pre-session

7.4.3. Initiation Phase

Once setup is complete, the user is instructed to put on the headset. Visual guidance and audio cues help the user position the device correctly, ensuring electrode contact and comfort. A quick check is conducted by asking the user to tilt his head forward and sideways to make sure the headset is correctly oriented. Once correct positioning is confirmed, a call-to-action (CTA) in the app prompts the user to start the session. A short message reminds the user to get comfortable before beginning. After confirmation, a five-second countdown begins, preparing the user for the start of stimulation. This sequence ensures the user is mentally and physically ready, minimizing stress or surprise as the session starts. (Figure 7-14)

Figure 7-14: Initiation

7.4.4. During Stimulation

During the stimulation phase, the app interface becomes minimal and calming. A simple progress bar, time remaining, and session progress percentage are displayed. Users have optional access to guided breathing exercises or ambient background sounds by enabling this in the settings, enhancing relaxation without distraction. A cancel button is also present, but it includes a strong warning that cancelling the session at this stage will invalidate it. The aim is to maintain a sense of calm and control, while discouraging unnecessary interruptions. (Figure 7-15)

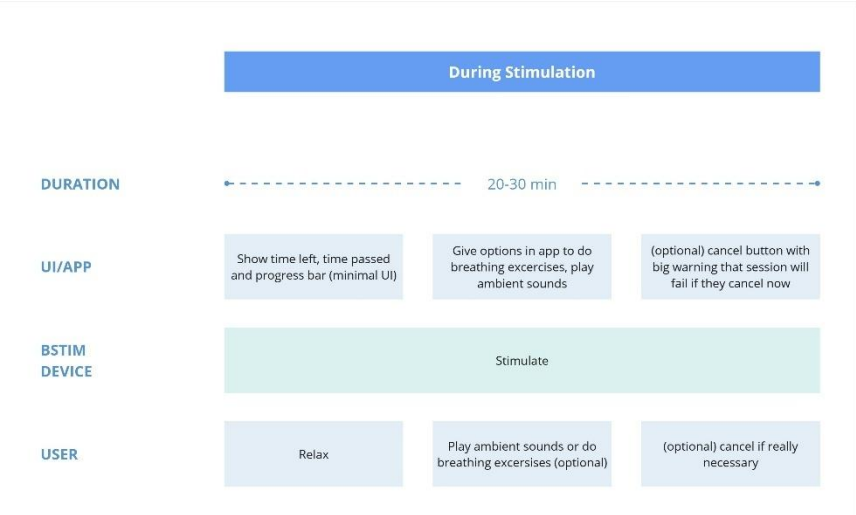

Figure 7-15: During stimulation

7.4.5. End of Session

As the session ends, a soft notification or melody signals that stimulation is concluding. The system begins a ramp-down sequence to gently reduce stimulation intensity. Once complete, the user is prompted to remove the headset, followed by a post-session checkup in the app. This includes questions regarding the user's mood, comfort, and any sensations such as tingling or pain. Upon completion, a positive reinforcement message is shown, congratulating the user on completing the session and reinforcing adherence. (Figure 7-16)

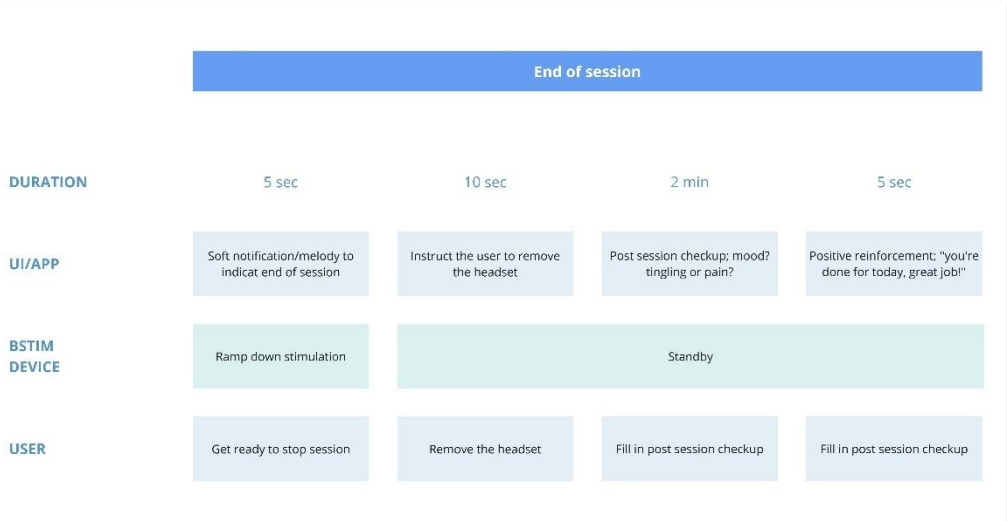

Figure 7-16: End of session

7.4.6. Post-Session

After the session, the app may suggest charging the device if battery levels are low. The user is also instructed to power down the headset and clean the device if necessary. This includes rinsing or drying the electrodes to maintain hygiene. These final steps ensure the device is properly maintained and ready for the next use. The session concludes with the device in standby or powered off, marking the end of the user journey. (Figure 7-17)

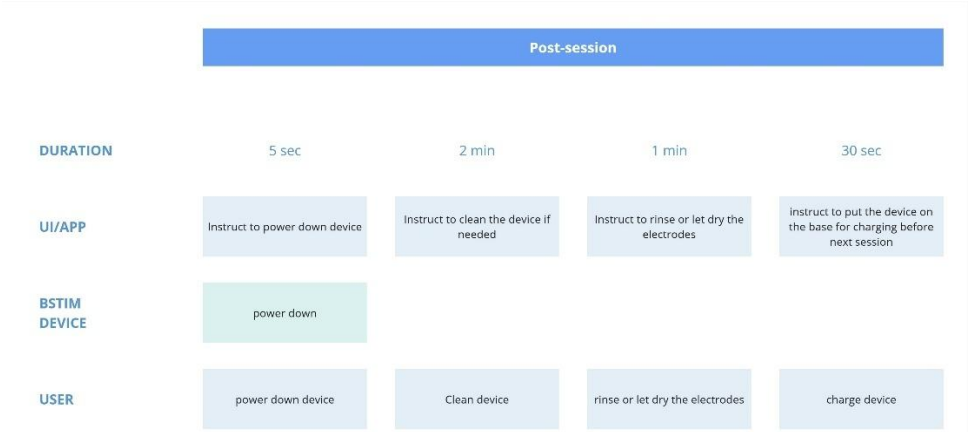

Figure 7-17: Post-session

The user experience mapping outlines a structured and intuitive journey that prioritizes clarity, safety, and ease of use across all phases of a stimulation session. From the initial supervised walkthrough to independent daily use, each step is designed to build user confidence while ensuring consistent and effective interaction with the B.stim system. This experience forms the foundation for the digital interface, which translates the physical and procedural aspects of the session into a clear and supportive app environment. In the following chapter, this user flow is implemented into a functional user interface design, developed to guide users through setup, monitoring, and completion of each session.

7.5. User Interface Design

To translate the defined user experience into a functional and accessible digital application, a prototype user interface (UI) is developed in Figma. This interface guides the user through each phase of the stimulation session, aligning with the steps defined in the UX mapping. The design prioritizes clarity, calmness, and medical trustworthiness, ensuring that both first-time and returning users can navigate the system with confidence and minimal effort.

The interface is intentionally kept minimal, using green as an accent color throughout the UI. Green is not only associated with calmness and focus in color psychology but is also recognized as the color of mental health awareness, reinforcing the therapeutic context of the B.stim device. The visual layout avoids unnecessary complexity, emphasizing large touch areas, clean typography, and progressive task flow.

Upon launching the app, the user is first asked to create an account. This account is linked to the medical professional's database. Once logged in, the user enters a main menu (Figure 7-18), which allows switching between two primary views: the agenda and the session interface.

The agenda section provides an overview of all completed, failed, and planned sessions. Sessions are color-coded to support easy recognition:

- Green for successfully completed sessions
- Red for failed or prematurely ended sessions
- Grey or neutral for upcoming sessions

This history offers transparency and helps users stay engaged with their treatment schedule. The app also displays today's session status (e.g., completed, planned, or pending), reinforcing daily adherence.

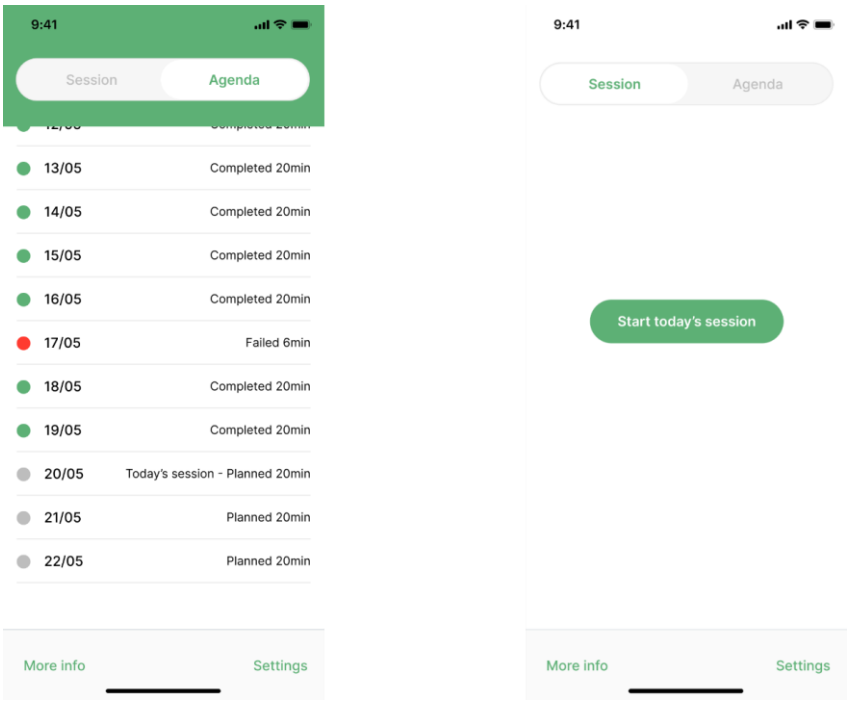

Figure 7-18: Main menu

The session interface is where the user initiates and walks through a full stimulation session. The UI mirrors the step-by-step structure defined in the UX map—from powering on the device and electrode preparation to placement guidance, impedance checks, and stimulation initiation. Each instruction is visually supported with clear language and a "Done" or "Back" button, allowing users to proceed at their own pace (Figure 7-19). A "Cancel session" option is available at every stage before stimulation begins, providing flexibility and control. However, once stimulation has started, cancelling results in a failed session, which is recorded in the agenda and marked accordingly.

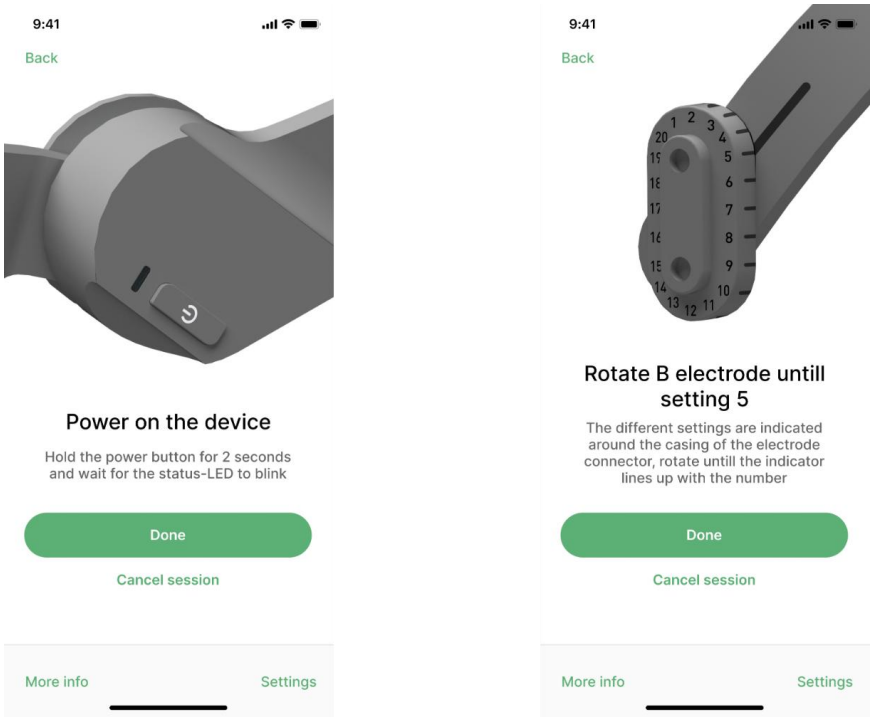

Figure 7-19: Instructions

During the session, the UI becomes even more minimal. A clean display shows the session progress, time remaining, and a discreet cancel button (with a warning). This interface supports focused and uninterrupted usage while still allowing the user to end the session if absolutely necessary.

Following the session, a brief questionnaire is presented to capture the user's experience. It asks about mood, any discomfort or tingling, and general satisfaction. This data is submitted to the linked medical professional for review. (Figure 7-20)

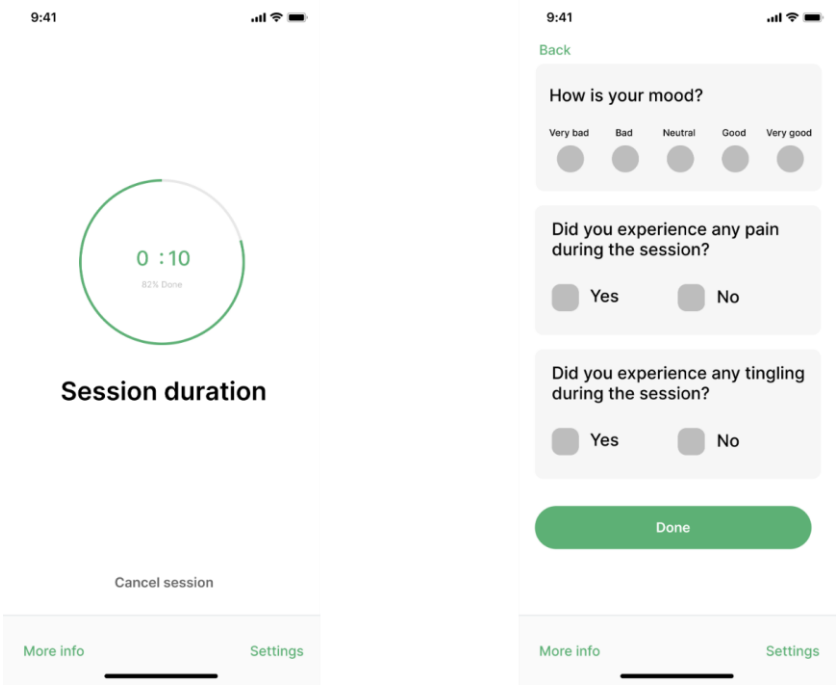

Figure 7-20: UI During and after session

Once the session ends, the UI transitions to removal and cleanup guidance. The user is instructed to take off the headset, rinse the electrode sponges, clean the device, and charge it for the next session. These steps are kept concise and visual to promote consistent maintenance and hygiene. After completion, the user is shown a positive confirmation message ("You're done for today, well done"), offering positive reinforcement and encouraging session completion in the future. (Figure 7-21)

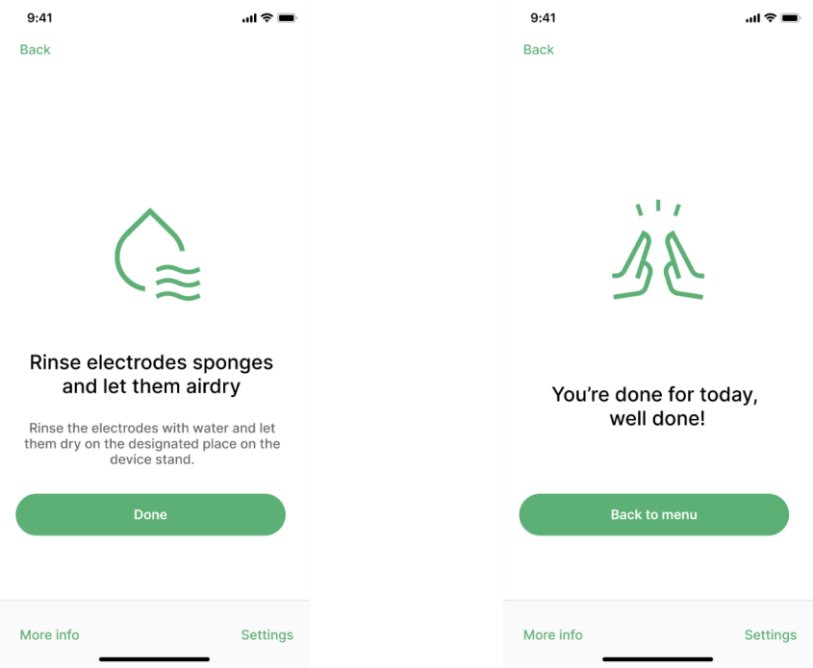

Figure 7-21: Instructions to end session

The Figma-designed user interface provides a digital layer that fully supports and reflects the B.stim user experience. By combining therapeutic calmness with clinical precision, the app ensures that users can navigate the session process independently while still feeling supported. The minimal layout, real-time guidance, and session tracking features enhance the product's usability and adherence potential. For the full interface flow, see Appendix G. This UI prototype now forms the foundation for usability testing.

Develop phase III marks a transition from technical feasibility to user-centered readiness. With electronics selected and integrated, materials refined, and a guided interface in place, the B.stim headset now offers a coherent and supportive experience for both patients and clinicians. Every interaction is structured for clarity, calmness, and safety. This phase ensures that the product is not only functional, but also focusses on a good user experience. This lays a solid foundation for final validation and user testing.

8 Final Validation

8.1. User Tests

To validate the integrated design of the B.stim headset, a usability test was conducted with both expert and layperson participants. The goal of this test was to assess the intuitiveness, comfort, and user experience of the full product system, including the headset, modular electrodes, sponge interface, saline preparation, and the Figma-based UI prototype. This test served as the first complete simulation of a home-based TES session and provided crucial feedback for refinement prior to clinical or real-world deployment.

8.1.1. Protocol

The test was conducted on-site at UZ Ghent and at the home of the laypersons using the final physical prototype of the B.stim headset and interface. Each participant received the following (Figure 8-1):

- A headset with modular electrodes
- Fake plastic electrodes with sponge sleeves to simulate rubber electrodes

- A saline basin and solution
- A phone with the interactive Figma UI prototype
- Pre- and post-session questionnaires
- A QR code linking to the app prototype

The participants got an explanation of all the different parts of the headset, this is to simulate the first guided session with the medical professional. Then, participants were guided by the app alone to simulate independent home use. The test followed the B.stim Usability Test Protocol, see Appendix H, which included a complete walkthrough of a typical stimulation session as described in the user experience map.

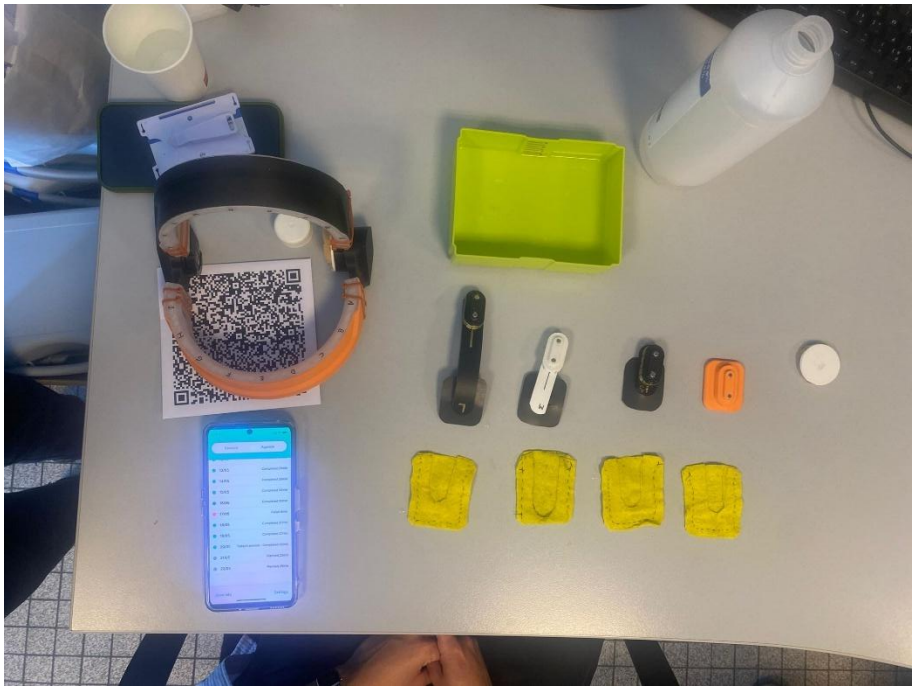

Figure 8-1: Usertest setup

Two participant groups were involved:

- Users familiar with TES devices, to benchmark usability against existing solutions
- Laypersons, to test onboarding, clarity of instructions, and UI intuitiveness

Each participant is asked a pre-test questionnaire assessing experience and expectations, and a post-test questionnaire evaluating confidence, comprehension, and interface feedback.

8.1.2. Results

A range of detailed observations were collected, leading to several consistent improvement points:

Electrode preparation

Participants were uncertain about how many sponges to prepare and how wet they should be. Some used too many sponges, others inserted them into saline instead of rinsing them under tap water. Clearer instructions and a video or gif instruction were repeatedly suggested. Experts also mentioned that with other benchmarks an infographic is included and that this would be nice to have.

Electrode insertion and identification

Users requested more clarity on how to slide the sponge over the electrode and how to identify which electrode should be used. Suggestions included pictures in the UI. It is important to note here that in the prototype the sponges are handmade from rags and that a universally fitting sponge would work better in this scenario.

Headset fit and interaction

Most users found the headset easy connect and setup but the fit was not good, it was still way to stiff and put a lot of pressure on the head. Because this is still a prototype that does not have the final materials, this problem is hopefully resolved with further development. Headset orientation was unclear for some, prompting suggestions like angle markers or an extra instruction step to identify the front. (Figure 8-2)

UI feedback and behavior

The app interface was generally rated as clear and calming, especially during the stimulation phase. Participants appreciated the cancel warning and found the progression intuitive

Cleaning and session wrap-up

Post-session cleaning instructions lacked precision. Participants requested more information on how much to clean and how to store parts. Some assumed the sponges should be rinsed in saline, which contradicts hygiene goals.

Trust and confidence

Participants reported feeling reassured when they saw or felt the magnetic connection “click” into place. This tactile feedback reinforced the perception of correct use. A suggestion was made to add a reminder not to remove the electrodes mid-session, to avoid damaging the setup or causing confusion.

Figure 8-2: User wearing headset

8.1.3. Conclusion

The user testing confirms that the B.stim product concept is fundamentally intuitive, well-structured, and well-received, but that improvements in guidance and clarity are needed for real-world use. Specific pain points include sponge preparation, electrode identification, and post-session care—areas where visual reinforcement and simplification are likely to improve performance. The UI was praised for its calming tone and structured flow, supporting the design direction. Insights from this test will be directly integrated into both hardware and interface refinements for the final version.

8.2. Functional Requirements Validation

To ensure that the final concept of the B.stim headset aligns with the project's original objectives, a validation of the Functional Requirements Document (FRD) is conducted. The FRD contains all performance, safety, usability, and technical criteria identified during the early design stages, based on literature review, stakeholder input, and regulatory context.
Each requirement in the FRD is revisited and cross-checked against the current state of the design. This includes:

- Direct verification through CAD evaluation (e.g., physical fit, material selection)
- Prototype testing results (e.g., modularity, comfort)
- Design decisions that demonstrate intentional compliance (e.g., IP protection, hygiene-compatible surfaces, modular electrode system)

Where requirements have not yet been fully verified they are marked as pending and noted for validation in the final test phase or in the future beyond the scope of this thesis. For example those depending on user testing and clinical validation. This structured validation confirms that the design meets its intended functional scope as much as is possible in the timeframe of this thesis.

The results of this FRD validation are summarized in a table, including each requirement, its current status (fulfilled / partially fulfilled / pending), and a short justification. This table can be found in Appendix I

The results show that the majority of the FRD criteria have been fulfilled or partially fulfilled within the scope of the thesis. Requirements that could not yet be verified are transparently marked as pending and scheduled for future validation. This ensures clarity on both the current performance of the prototype and the areas where further development is needed.

In summary, the current B.stim concept demonstrates a strong level of compliance with the functional expectations established during the early design phases. This structured validation confirms that the prototype is on track for further development and real-world testing.

8.3. uFMEA

The following usability Failure Modes and Effects Analysis (FMEA) identifies realistic, device-specific risks for each major subsystem of the final B.stim headset design (including subsequent refinements). Each entry includes the failure mode, cause, effect (hazardous situation), possible clinical harm, initial risk ratings (Severity, Probability, and Risk Priority Number), implemented risk controls (design features or protective measures), residual risk ratings after controls, whether new risks are introduced by the controls, any need for safety information (e.g. user training or labeling), and evidence of effectiveness from testing or validation.

Severity (S) and Probability (P) are scored 1–5 (5 = highest). RPN is S×P. All risks are considered without prioritization; clinical safety, usability, technical robustness, and regulatory implications are captured for each subsystem. A preview of this uFMEA can be seen in Table 8-1.

Table 8-1: uFMEA preview

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Modular electrodes	During session	Electrode sponge dries out (high impedance)	User fails to adequately wet sponge; extended use dries it	Poor conduction – current pathway becomes resistive or open, causing ineffective stimulation or hot spots	Skin irritation/burn; therapy under-dose (depression not treated)	4	3	12	**Design:** Constant-current source (LT3092) maintains stable output despite impedance changes. **Protective:** Impedance monitoring injects a test current and halts stimulation if contact is poor; app instructs user to re-wet electrodes.	1	1	1	No	Yes (soak pads)	Impedance safety feature integration was verified conceptually – it reduces risk of ineffective or harmful stimulation (design review). Initial supervised sessions ensure users properly prepare electrodes.
	During session	Electrode module detaches or loses contact	Insecure seating in headband slot; sudden movement or worn connector	Open circuit or intermittent contact – stimulation stops unexpectedly or fluctuates; potentially startling user	Therapy interruption (missed dose); transient shock/buzz sensation on reconnection	3	2	6	**Design:** Spring-loaded pogo-pin connectors maintain contact even if module is not optimally seated. Headset frame provides constant gentle pressure to keep electrodes in place. **Protective:** Impedance check stops current on loss of contact, preventing sudden surges; user instructed to perform a "shake test" (head tilt) to confirm secure fit.	2	1	2	No	Yes (fit check)	Prototype testing of Concept 2 revealed contact consistency issues, which were addressed by the modular electrode design (pogo pins and elastic pressure). Usability checks (tilt head test) are built into the session startup to verify secure contact.
	Setup (placement)	Electrode placed at wrong position/orientation	User error in following placement instructions (e.g. swaps anode/cathode or wrong head location)	Stimulation delivered to incorrect brain region or reversed montage – reduced efficacy or unintended effects	Ineffective treatment (no clinical improvement); possible suboptimal stimulation effect)	4	2	8	**Design:** Modular slot system with clearly defined positions on bands to guide placement. **Protective:** First session is supervised by a professional who teaches correct electrode positioning. The mobile app provides visual/auditory cues and confirms when electrodes are in the correct slots. Clear labeling (color-coding or markers) distinguishes electrode polarity in the kit.	2	1	2	No	Yes (training & app)	Usability tests identified inaccurate placement as a threat without proper guidance. This informed the inclusion of app-driven placement guidance and training. During the initial guided use, correct electrode placement was ensured and user confidence improved.
	During use (extended arm electrode)	Extended electrode arm fails to reach/maintain position	Mechanical joint of arm slips or rotary contact (slip ring) fails after wear or mis-adjustment	Electrode cannot be positioned at target area or loses electrical connection when arm rotates, limiting therapy to that site	Incomplete stimulation of intended area (reduced clinical effect); user frustration adjusting device	3	2	6	**Design:** Rotating arm includes a rated slip ring that provides continuous electrical contact through all angles, preventing wire twisting or disconnection. Arm hinge designed with sufficient friction/tension to hold the electrode in place once positioned (no free flop in normal use). **Protective:** If an extended electrode fails, therapy can still continue with alternate electrode configuration (spare standard electrode provided). Plental maintenance replaces any worn or loose arm components.	2	1	2	No	Possibly (alternate electrode)	The modular electrode concept was developed to improve placement flexibility. Any mechanical weakness would be caught during rental inspection and addressed (replacement of worn parts).

The complete use-oriented Failure Modes and Effects Analysis (uFMEA) can be consulted in Appendix J.

All identified risks have been addressed through design iterations, inherent safety features, and procedural controls. The residual risks are deemed acceptable for the intended home-use context of B.stim, with validations via prototypes, usability testing, and expert input confirming the effectiveness of the mitigation measures. Each control's implementation and effectiveness will continue to be verified in ongoing design validation, future design and future clinical testing to ensure regulatory compliance and patient safety. All risk controls did not introduce new unintended risks beyond those noted (and none of the above controls degrade the safety or performance of the device). The FMEA will be updated as needed with any new findings from subsequent testing or user feedback to maintain a comprehensive risk management process.

9 Deliver

This chapter documents the final outcome of the B.stim development process. It consolidates all key design decisions, technical specifications, and functional elements into a comprehensive overview of the final product. The deliverables include detailed component breakdowns, cost analysis, CAD documentation, and visual representations of the device in use. Together, these outputs provide a complete picture of the B.stim headset as a ready-for-validation prototype suitable for both user testing and stakeholder presentation.

9.1. Final Design

The final design of the B.Stim headset is a wearable transcranial electrical stimulation device optimized for home-based depression therapy. It consists of a lightweight adjustable headband, a central module housing the electronics and battery, and modular electrode assemblies that can be positioned according to prescribed montages (Figure 9-1, 9-2). The overall form factor is minimalist and ergonomic, resembling a modern consumer headset rather than a clinical apparatus. This approachable design language is intended to convey professionalism and safety while encouraging user trust and regular use.

Figure 9-1: Headset with electrodes attached

Figure 9-2: Headset and electrodes separate

9.1.1. Form and Product Architecture

The headset's architecture is organized into three primary elements: the headband frame, the central module, and the detachable electrode modules (Figure 9-3, 9-4, 9-5). The headband frame provides structural support and fitting; it curves around the head in a gentle arc, ensuring a stable yet comfortable grip on the cranium. All edges and contours of the frame are smoothly rounded to avoid pressure points, reflecting a user-centered form development. The central module, located in between the headband (positioned above the ear), encloses the device's electronic circuitry and power source. This module is kept as compact as possible and balanced in weight to prevent the headset from feeling side-heavy or unstable. The modular electrodes attach to the connection ports included in the headband at evenly spaced locations. Each electrode module contains a rubber snap on electrode, sponge electrode sleeve and a mating connector part. The final configuration supports free placement of electrodes over the head. This modular architecture allows the device to target standard clinical electrode positions (such as the left and right dorsolateral prefrontal cortex at F3 and F4 in the 10–20 EEG system) while also accommodating alternative placements if required by different treatment protocols. The full possible stimulation coverage can be seen in Figure 9-6.

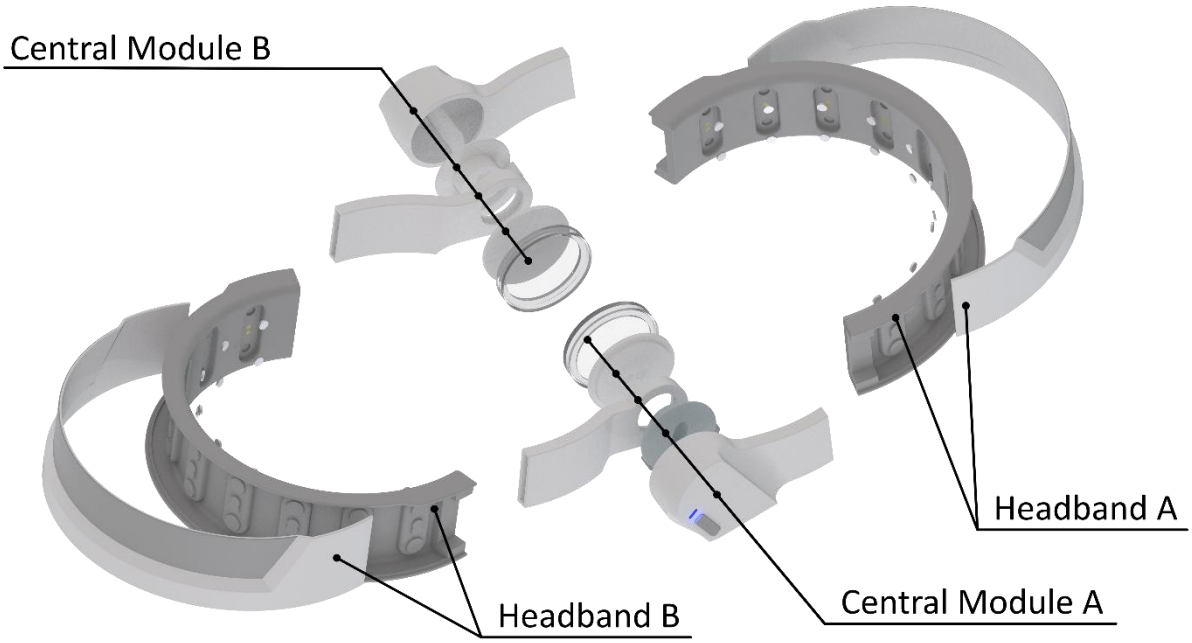

Figure 9-3: Exploded view of headset

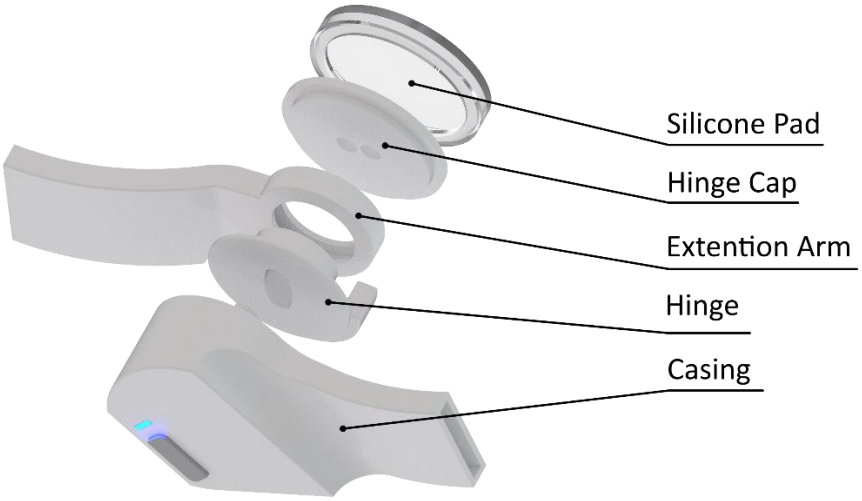

Figure 9-4: Exploded view of central module

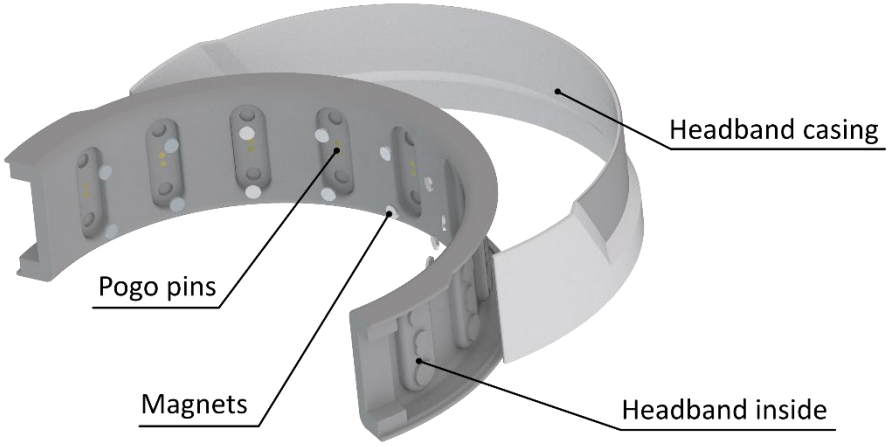

Figure 9-5: Exploded view headband

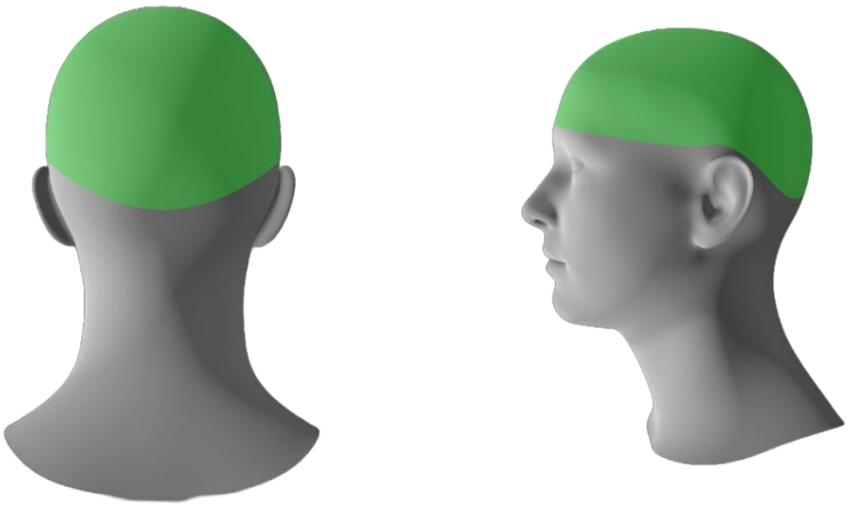

Figure 9-6: Headset coverage

The form of the B.Stim headset deliberately takes inspiration from familiar consumer electronics (notably, headphone designs) to put users at ease. All outward-facing components have a clean, matte finish with minimal visual clutter. There are no excessive straps or dangling wires; instead, the wiring for electrodes is integrated into the frame and routed through the extension arms into the central module. This integration contributes both to aesthetics and to safety by concealing cables. The final design presents a professional yet non-intimidating appearance, aligning with earlier findings that devices perceived as overly “medical” can be intimidating to patients. The visual simplicity also reflects Concept 3 from the development phase, which was favored for its intuitive and sleek form. By building on that concept’s strengths, the final design achieves a balanced, approachable look that instills confidence in home users while meeting clinical functionality.

9.1.2. Adjustable sizing mechanism

To fit a wide range of adult head sizes and shapes, the B.Stim headset incorporates a precise yet simple sizing mechanism. The central module features an extension slider that allows the headband circumference to expand or contract, accommodating head circumference variability (the 5th to 95th percentile of users). The mechanism operates by a telescoping action hidden within the headband: the two halves of the band slide relative to each other and lock at the desired length by friction. This adjustment is easy to perform and does not require any tools, users can simply pull or push the band until it rests snugly. This solution was chosen after evaluating several concepts for adjustability; it provides a single, intuitive adjustment point in contrast to earlier multi-point adjustment. In other words, the final design minimizes user effort in fitting, which is critical for encouraging regular home use.

9.1.3. Ergonomics and Comfort

Ergonomic comfort was a big design driver, given that users may wear the headset for daily stimulation sessions typically lasting around 20–30 minutes. The final B.Stim design addresses comfort through weight distribution, padding, and form geometry. The device's mass is balanced around the head: heavier components (like the battery and electronics) are positioned in the central module towards the side of the head. A small internal counterweight is integrated into the central module to fine-tune balance, ensuring the headset's center of gravity aligns roughly with the head's central axis. By achieving this balance, the headset stays securely in place during use without requiring overly tight straps.

Key contact points between the headset and the user's head are cushioned. A removable silicone pad lines the inner side of the central module where it touches the side of the head, distributing pressure over a broader area and providing a soft contact point against the skin. These pads are made of medical-grade silicone, which is hypoallergenic and easy to clean, ensuring both comfort and hygiene. The use of removable padding means they can be periodically washed or replaced, which is important for a device intended for frequent personal use (and also supports a rental or multi-user scenario by allowing thorough cleaning between users).

The ergonomic form has also been tailored to accommodate users with accessories or varied anatomy. The headset's contact points are positioned to clear the ears, allowing it to be worn comfortably with eyeglasses or earbuds. There are no parts that block the eyes or cover the face, avoiding any claustrophobic sensation and allowing the user to carry on with light activities (like reading or watching a screen) during a stimulation session. The electrode modules themselves are designed to conform gently to the scalp: each module is mounted via a rotational joint (a slip-ring mechanism) that lets it be placed with 360 degrees of freedom. This arm is curved and slightly flexible so that it follows the head shape. This means that regardless of slight differences in head shape or positioning angle, the entire surface of the sponge electrode can make uniform contact with the skin, preventing pressure hotspots and ensuring consistent current distribution. Overall, these ergonomic considerations fulfill the earlier user requirement that the device "be as comfortable and unobtrusive as possible" to encourage adherence. Early prototype testing with users confirmed the effectiveness of these measures.

9.1.4. Modular Electrode System

A defining feature of the B.Stim headset is its modular electrode system, which enables a high degree of personalization in therapy. Unlike conventional home-use tES devices that fix electrodes in one or two static positions, B.Stim allows electrodes to be detached, reattached, and repositioned in accordance with different treatment montages or individual anatomical considerations. The system is composed of multiple electrode modules (Figure 9-7) and corresponding mounting ports on the headset: for the final design, the headband provides nine mounting points on each side of the headband, so front and back together have 18 possible connection points. Each mounting point is a recessed magnetic connector that aligns and secures the electrode module. Strong neodymium magnets embedded in the module and the port attract each other, guiding the module into the correct position with a satisfying snap. Simultaneously, a set of

spring-loaded pogo pin contacts in the port mate, forming the electrical connection for the stimulation current. The magnets are switched in polarization on the upper and lower side of the connection port to ensure that the electrodes are correctly attached for the electrical connection. This prevents reverse connection of the modular electrodes to the headband. The magnetic attachment and slip-ring allow the electrode module to rotate to the designated orientation for the stimulation, and also makes attaching/removing modules extremely intuitive. The user can simply pull a module off or click it on, with no cables to plug in or clamps to tighten.

The electrode modules themselves are with a snap-on electrode connection (Figure 9-8, 9-9). On these connections the rubber electrodes can be snapped on (electrodes of approximately 5×7 cm, as chosen in the final specification). Each module is made from a a plastic casing that runs wires from the pogo pin connection trough the slip ring to the snap on connection piece. The sponge can be easily taken of of the rubber electrode for wetting with saline before a session and cleaned or replaced as needed. By using saline sponge electrodes, the design ensures consistent contact impedance and user comfort, addressing earlier concerns about dry electrodes causing skin irritation or unreliable contact. The modular design means that if future electrode technologies (improved dry electrodes, EEG sensors during TES stimulation) become viable, new modules could be developed that fit the same ports, without redesigning the entire headset. This provides a degree of future-proofing.

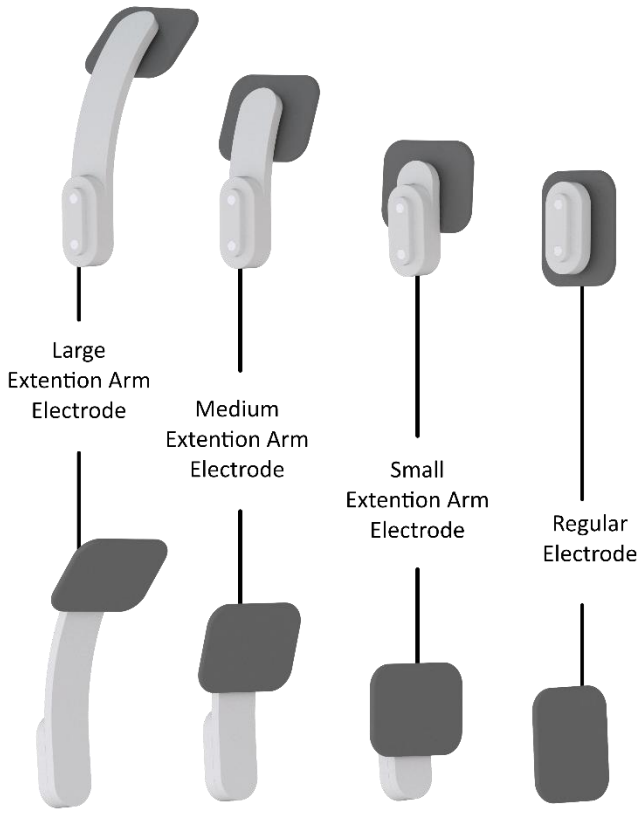

Figure 9-7: Modular electrodes

Figure 9-8: Snap-on electrodes

Figure 9-9: Snap-on connection

This modular electrode system directly addresses the user and clinical need for flexible electrode positioning. For example, a typical depression treatment montage might require an anode at F3 (left forehead) and a cathode at F4 (right forehead). In another scenario, a clinician might wish to experiment with a montage placing an electrode at top-center (Pz position) as a reference. B.Stim can accommodate both by allowing the user or clinician to attach the electrode modules to the corresponding port locations on the headband. The design thereby avoids the “one-size-fits-all montage” limitation seen in some commercial devices, and it enables personalization: each patient’s headset configuration can be tailored to their prescribed montage. Yet, it achieves this flexibility without overwhelming the user. The modular connections are straightforward and error-proof. Magnets make sure that a module will only latch in the correct orientation for safety.

9.1.5. Materials and finishes

The choice of materials and surface finishes for the final design was guided by requirements for durability, comfort, biocompatibility, and aesthetics. The main structural components of the headset (the headband frame, central module casing, and electrode casings) are manufactured from injection-molded ABS/PC plastic. ABS/PC was selected for its excellent balance of strength, light weight, and moldability. These characteristics are critical for producing a robust yet comfortable device. The plastic parts have a neutral matte finish that is both visually refined and practical: a matte texture hides fingerprints and minor scuffs, and it presents a calm, non-reflective appearance. The color scheme chosen is a soft neutral palette (a light gray or off-white base color for the headband and modules) to avoid the stark, clinical look of pure white but still evoke a clean medical device aesthetic.

All user-contact materials are chosen with safety and comfort in mind. The ABS/PC housing is skin-safe and free of rough seams at touch points, and the silicone elastomer pads (used in the cushioning and electrode interfaces) are medical grade, ensuring they do not cause irritation during contact with skin and can withstand repeated cleaning. The device's assembly is designed to be water-resistant to a degree: critical seams (such as where the central module closes and where electrode ports reside) incorporate thin silicone gaskets. This sealing prevents ingress of sweat or saline drips from the wet electrodes, allowing the user to wipe down the device with a damp cloth after use without damaging the electronics. While not intended for full submersion, the headset can tolerate occasional light rinsing of the pads or surfaces, which is important for hygiene maintenance. The finish on plastic parts is also chemical-resistant enough to handle common disinfectant wipes, addressing infection control concerns especially if the device is used in a rental model by multiple patients.

9.1.5.1. Placement indicators

To ensure correct and intuitive assembly of the modular electrodes, the final design incorporates a system of clearly visible placement indicators directly integrated into the headset. These indicators serve to guide the user in positioning each component accurately, thereby minimizing the risk of user error and enhancing the overall usability of the device during setup.

Above each electrode connection port on the headset, alphabetical labels ranging from A to R are printed (Figure 9-10), corresponding to predefined stimulation locations. This alphabetical coding allows users to easily match each modular electrode to its appropriate port. In addition, the modular electrodes themselves feature a circular arrangement of numerical markings, from 1 to 8, printed around their outer perimeter (Figure 9-11). These numerical cues are supplemented by half-step markings (indicated with lines) to guide users in achieving the correct rotational alignment, which is essential for correct placement and consistent stimulation performance.

To further support precise positioning, the central module of the headset includes indicators to set the degree of the folding axis. Going from 1 to 12, dividing the 180 degrees of freedom into 15 degree parts, they allow for precise positioning if the headset Figure 9-12). These degree markings enable the user to set the headset at a specific angle, supporting a repeatable and anatomically correct placement tailored to the user's head shape and intended stimulation target.

All of these visual indicators are applied as a durable printed finish directly onto the selected materials of the device, using techniques such as pad printing. This method ensures high-resolution, long-lasting visibility of the indicators on the curved and textured surfaces typical of ABS and other medical-grade plastics used in the device's construction.

Together, this multi-layered visual system enhances the ease of use of the B.stim headset, supporting accurate, repeatable electrode placement in both clinical and home settings.

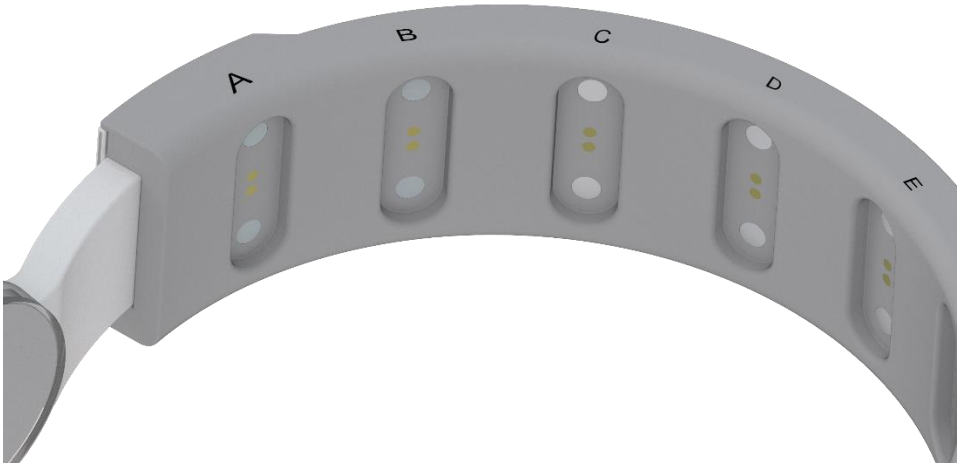

Figure 9-10: Connection port labels

Figure 9-11: Electrode orientation markings

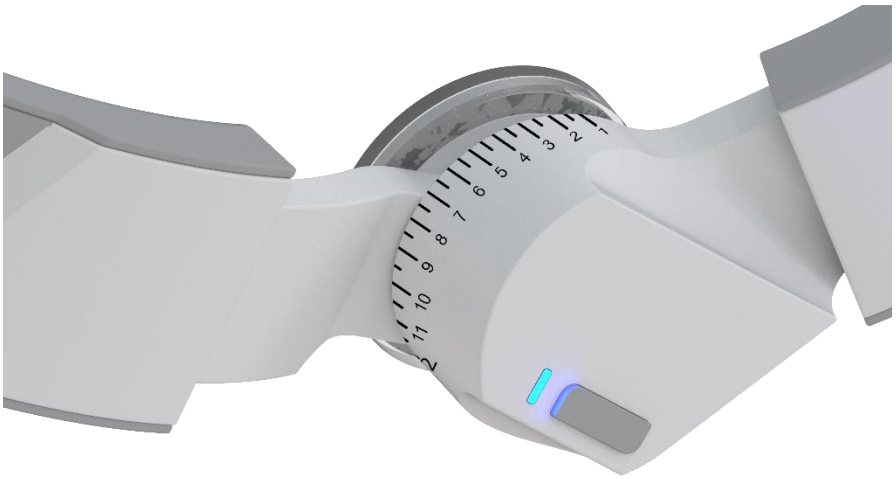

Figure 9-12: Folding degree markings

9.1.6. Electronics and Component Integration (Scope and Future Work)

Within the final physical design, a provision is made for all necessary electronic components to deliver the intended TES functionality. The central module houses a custom-designed printed circuit board (PCB) which includes a low-power microcontroller unit (for example, the Seeed XIAO ESP32-C3 module was selected in the prototyping phase for its integrated Bluetooth connectivity and sufficient processing capability). This microcontroller handles control of the stimulation parameters and communicates with a companion application (a smartphone app) to allow clinicians or users to set the treatment program. The stimulation circuit on the PCB is built around a precision programmable current source and a digital-to-analog converter, capable of delivering the controlled low-intensity currents (on the order of 1–2 mA) required for tES. Supporting this are an operational amplifier and safety circuitry including an analog switch network for routing current to the selected electrode pair, and a galvanic isolation transformer to protect the user from any surges or faults. An important feature of the electronics is the inclusion of an electrode-tissue impedance monitoring system: the circuit continuously measures the impedance at each electrode contact. If an electrode loses contact or if the impedance rises above a safe threshold (indicating, for example, a dry sponge or poor connection), the system can alert the user (via an app notification) and automatically pause or adjust the stimulation. This functionality directly addresses safety requirements by ensuring that the device operates only under proper conditions, thereby reducing the risk of ineffective or uneven stimulation.

Power is supplied by a compact rechargeable lithium-ion polymer battery (approximately 3.7 V, 120 mAh). This cell is mounted securely inside the central module. While relatively small in capacity, the battery was chosen to keep the headset light and the casing as small as possible; it provides enough charge for multiple stimulation sessions per charge (given the low current draw of tES and intermittent usage). Recharging is accomplished via a USB port on the device (the final design integrates a USB-C connector on the underside of the central module for easy access). A single multifunction power button is located on the side of the central module; pressing this turns the device on or off, and an adjacent LED indicator (discreetly embedded under the housing) conveys device status. By keeping the on-device interface minimal the design aligns with user feedback favoring simplicity. All advanced controls and session programming are handled in the companion app, meaning the hardware remains uncluttered and user-friendly.

It should be noted that while the final design specifies and allocates space for all these electronic components, detailed development of the electronics (PCB layout, firmware programming, and regulatory electrical safety testing) is beyond the scope of this thesis. The current design phase focused on identifying suitable components and ensuring the physical housing can accommodate them (for example, verifying that the PCB and battery fit within the central module

dimensions, and that wiring can be routed through the headband to the electrodes). The electronic component selection was made in consultation with preliminary experts' input and benchmark data, but a dedicated electronics engineer would be required in future work to refine the circuit design, optimize power management, and fully validate the system's performance to medical device standards. In essence, the thesis delivers the integrated design concept: a product where the industrial design and system architecture are defined, and all components have a place and purpose. Further electronics development is recommended as a next step in the project, ideally undertaken by specialists in biomedical electronics. These include improving the impedance sensing algorithm, ensuring compliance with IEC medical device electrical safety norms, and enhancing the firmware for user interface By clearly delineating this boundary, the project ensures that the physical design is robust and future-proof while acknowledging that electronic optimization remains an ongoing effort.

9.1.7. Charging base (Concept)

In addition to the headset itself, a conceptual charging and storage base was developed to support the user in the proper care, recharging, and maintenance of the B.stim system (Figure 9-13). This base is designed to serve as a central station for post-session handling, contributing to improved usability, hygiene, and product longevity.

The charging base features a dedicated, form-fitting slot for the headset. When the headset is placed into this slot after a stimulation session, charging is initiated automatically via integrated contact points. This design ensures a seamless user experience by removing the need for manual cable connections, reducing the chance of improper charging or damage to connectors.

To accommodate the modular electrodes, the base includes a series of dedicated storage compartments. These allow users to safely store each electrode module when not in use, protecting them from damage and maintaining organization. Adjacent to this storage area is a built-in drying rack specifically designed for the sponge-covered electrodes. After a stimulation session, these sponge sleeves require drying to maintain hygiene and prevent microbial growth. The drying rack is strategically positioned directly above a detachable basin, which also functions as the container used for wetting the sponges with saline solution prior to a session. This vertical configuration promotes a logical and ergonomic workflow, guiding the user from sponge wetting, to stimulation, to drying and storage.

Together, the charging base functions as an all-in-one accessory that supports the daily use and upkeep of the B.stim device, emphasizing hygiene, ease of use, and system integration within the user's home environment.

Figure 9-13: Charging base concept

9.1.8. User Interface

The final user interface (UI) design has been refined based on insights gathered during user testing, with the aim of facilitating a smooth and error-free transcranial electrical stimulation (TES) session. The core structure of the session which is divided into clearly defined sequential phases remains consistent with the earlier iterations. However, targeted improvements have been implemented to address steps that users previously found ambiguous or difficult to interpret. These include extra indications to help users identify the front of the device, the correct folding angle and the correct rinsing procedure after a stimulation session.

Additional textual explanations and visual prompts have been integrated into these critical phases to enhance user understanding and reduce cognitive load during operation. These refinements aim to increase user confidence, improve compliance, and ensure the correct setup and execution of the stimulation protocol in a home environment.

For future development, the interface could be further enhanced through the incorporation of dynamic instructional media, such as animated GIFs or short tutorial videos. These elements would offer real-time, step-by-step visual guidance, making the interaction more intuitive. This would be particularly helpfull for first-time users or those with limited technical experience. While the current prototype establishes a solid foundation for guided use, the implementation of these multimedia elements is considered a future iteration outside the present scope of the thesis.

9.1.9. Assembly

The assembly process of the B.stim headset has been conceptually designed to be simple, efficient, and suited for small-scale production or manual assembly. The modular construction ensures that all components can be assembled with minimal tools and limited risk of error, reflecting a focus on ease of maintenance and user accessibility.

Assembly begins with the integration of the electronic components into the central module. Once the internal circuitry is securely positioned, the casing is closed using a hinged cover that is fastened with screws to ensure structural stability. These screws are concealed beneath the soft silicone cap, preserving the clean appearance of the device while also improving comfort and safety.

For the headband, the flexible inner band is inserted into a precisely fitting recessed slot within the outer casing. The interface is designed to align naturally, after which the structure is secured with two screws on each side. This layered configuration supports both robustness and ergonomic flexibility, allowing the headset to adapt comfortably to different head shapes.

It is important to note that the current assembly approach remains largely conceptual. While the design demonstrates the intended construction logic, not all components have been fully optimized for streamlined production or tooling considerations. Future development phases will need to address these aspects in more detail, with a focus on design for assembly (DFA) principles and manufacturability. This conceptual assembly thus serves as a basis for further refinement and industrialization.

9.1.10. Cost estimate

9.1.10.1. Bill of materials

To support the manufacturing and prototyping of the B.stim headset, a detailed Bill of Materials (BOM) has been compiled. This list outlines all critical electrical components necessary for device functionality, accompanied by unit cost estimates based on pricing for batch sizes between 100 and 1,000 units. The BOM provides a foundational reference for estimating production feasibility and guiding supply chain planning.

Each component is sourced from established distributors such as Digi-Key and Mouser, ensuring availability and transparency in pricing. The full BOM, including pricing breakdowns and component sourcing, is included in Appendix K.

This BOM serves as a critical input for the broader cost estimation analysis, bridging the transition from prototype to scalable production.

9.1.10.2. Total cost estimate

In addition to the Bill of Materials, a full cost estimate has been prepared to evaluate the total expected expenditure per unit for a production run of 1,000 units. This estimate includes not only component costs, but also operational expenses and necessary investments for launching the product. (Table 9-1)

Table 9-1: Cost estimate

Category	Estimated Cost	Cost/Unit (1000pc)
Bill of materials	/	€227 - €338
Assembly & testing	/	€20 – €30
Certification	€30 000	€ 30
Packaging & logistics	/	€10 – €15
App development	€50 000-€100 000	€50-€100
Total		€337-€513

This estimation serves as a guideline for understanding the financial viability of production and market pricing. It highlights areas with fixed startup costs (certification, app development) versus variable per-unit costs (materials, packaging), supporting future business planning and investment decisions.

9.2. CAD Design

To support the transition from conceptual development to a manufacturable prototype, the B.stim headset is fully developed in a 3D CAD environment. The CAD model consolidates all mechanical and spatial design decisions made

throughout the project, including the integration of electronic components, modular electrode mechanisms, and ergonomic features. This digital model serves as a technical foundation for prototyping, production preparation, and communication with engineering and manufacturing stakeholders.

The design process is executed iteratively across three development phases. Initial models were used to test spatial feasibility, followed by more refined assemblies that incorporated updated component placements and wiring pathways. Particular attention is paid to the rotating band structure, the central module geometry, and routing space for electronics, ensuring that the product is both compact and functional.

The CAD design includes:

- All modular components of the headset (headband, central module, modular electrodes)
- Integration points for electronic hardware and connectors
- Internal volume to accommodate custom PCBs
- Defined locations for interface elements such as the power button and status LED
- Features to allow cable routing, connector placement, and snap-fit joints

To support prototyping and production preparation, a full set of technical drawings is included in this chapter. These drawings detail part dimensions making them suitable for supplier communication or future work. For the central module, some parts are only included once because the second part is a mirrored version of the shown part.

The CAD files also serve as the base for rendering and visual documentation of the product, shown in the subsequent chapter. Combined with prototype testing and validation, the CAD output ensures that the B.stim design is technically feasible and ready for translation into a physical, user-ready device. The technical drawings can be seen in Appendix J.

9.3. Final Prototype

As part of the final deliverables, a complete physical prototype of the B.stim headset is produced to embody the finalized design as developed through CAD modelling and functional detailing. This prototype is fabricated through 3D printing and represents the current design state in full scale, serving as a tangible validation of the form, structure, and modularity of the device. (Figure 9-14, 9-15, 9-16)

The prototype is printed in PLA using FDM technology and includes:

- The full headband structure with integrated rotation mechanism
- A scaled central module with internal space for electronics
- All mounting interfaces for the modular electrodes
- Simulated features such as the power button, status LED, and electrode connection ports

While the prototype is not electronically functional, it faithfully represents the mechanical aspects of the product and was used during user testing to evaluate wearability, usability, and interaction with the electrode system and UI.

This 3D-printed version serves several key purposes within the delivery phase:

- It acts as a physical confirmation of the CAD design’s manufacturability and spatial accuracy
- It supports demonstration and communication with stakeholders and potential production partners
- It provides the foundation for final design validation, enabling feedback on form factor, size, ergonomics, and electrode mounting before entering future production iterations.

Photographic documentation of the prototype is included in this section, showing the assembled device from various angles as well as in simulated usage contexts. These images help communicate the practical and visual outcome of the B.stim development process and demonstrate readiness for functional prototyping and clinical evaluation.

Figure 9-14: Headset prototype

Figure 9-15: Modular electrodes prototype

Figure 9-16: Headset with electrodes prototype

9.4. Renders

To conclude the delivery phase, a series of high-fidelity renders is produced to communicate the final design vision of the B.stim headset. These visualizations are based on the latest CAD model and reflect all decisions made throughout the development process regarding form, materials, modularity, and interface layout.
The renders serve multiple purposes:

- They provide a realistic representation of the product as it is intended to be produced
- They support stakeholder presentations, external communication, and future fundraising or production discussions
- They illustrate the product in its intended use context, helping to convey how the device interacts with the user

9.4.1. Render Categories

Component Renders:
These images display individual elements of the system, such as the headset structure, modular electrodes, central module, and charging base. Each component is shown in isolation to highlight its geometry, function, and material characteristics. (Figure 9-20, 9-21, 9-22, 9-23)

Full Product Renders:
Assembled views of the B.stim headset are presented to demonstrate the complete system. These include views from various angles, showcasing the rotating band design, electrode attachment zones, and interface positioning. (Figure 9-17, 9-18, 9-19)

Together, these renders serve as a visual deliverable of the B.stim project, reinforcing the product's design intent, technical resolution, and readiness for future development steps such as engineering validation and manufacturing preparation. They represent the final integration of usability, technology, and therapeutic application—captured in a format suitable for professional communication and product introduction.

Figure 9-17: Headset folded open

Figure 9-18: Headset folded closed

Figure 9-19: Headset with electrodes top view

Figure 9-20: Regular electrode

Figure 9-21: Extention arm electrode small

Figure 9-22: Extention arm electrode medium

Figure 9-23: Extention arm electrode large

10 Societal and Sustainability Reflection

The development of B.Stim, a transcranial electrical stimulation headset for depression, carries broad societal implications across health, sustainability, ethics, and global contexts. This reflection examines how the project aligns with international goals and values and how an industrial design approach enhances its positive impact. For this the United Nations Sustainable Development Goals (SDGs) are consulted

10.1. Alignment with Sustainable Development Goals (SDGs)

10.1.1. SDG 3: Good Health and Well-Being

B.Stim directly supports SDG 3, which aims to ensure healthy lives and promote well-being for all. By providing a new option for treating depression, a condition affecting an estimated 280 million people worldwide, the project addresses mental health as a global health priority. Target 3.4 of SDG 3 specifically calls for promotion of mental health and the

reduction of premature mortality from non-communicable diseases. Depression is a leading cause of disability and can lead to suicide, particularly among young people. By designing an accessible home-based therapy for depression, B.Stim contributes to improving mental health outcomes and filling treatment gaps. It enables more people to receive effective treatment, especially those who might not respond to or cannot access conventional care, thus promoting well-being in alignment with SDG 3.

10.1.2. SDG 8: Decent Work and Economic Growth

Mental health is not only a medical concern but also an economic one. Depression and anxiety are estimated to cost the global economy around USD $1 trillion per year in lost productivity due to factors like absenteeism and reduced work performance[28]. By improving depression treatment and potentially helping individuals recover and return to productive life, B.Stim can have a positive economic impact. Better mental health care supports decent work by enabling individuals to engage in employment and community life more fully. Furthermore, the project itself exemplifies innovation-driven growth (related to SDG 8) by potentially creating new opportunities in the medical device industry. The development and production of such neuromodulation devices can generate skilled jobs and foster sustainable economic growth in the health-tech sector, provided that labor practices in manufacturing and distribution uphold decent work standards.

10.1.3. SDG 12: Responsible Consumption and Production

The B.Stim project incorporates sustainable design principles that align with SDG 12, aiming to reduce environmental impact through responsible consumption and production. As electronic medical devices can significantly contribute to global e-waste, which is estimated at 62 million tonnes in 2022 with only 22% properly recycled, B.Stim addresses this challenge through a circular design strategy. One proposed solution is a rental-based product-service system, where devices are not sold outright but instead provided through a subscription or loan model. After use, headsets are returned, refurbished, and redistributed. This approach ensures components such as electrodes and batteries can be inspected, replaced, or upgraded as needed, thereby extending the product's lifecycle and minimizing unnecessary waste. By prioritizing durability, repairability, and reuse, B.Stim actively contributes to reducing material consumption and waste generation, fully supporting the objectives of SDG 12.

10.2. Ethics, Equity, and Design Justice in Healthcare Technology

Beyond the SDGs, ethical considerations and inclusive design principles are central to B.Stim's societal impact. The device is designed in line with design justice frameworks that seek to ensure fair distribution of benefits and burdens among all stakeholders. Design justice is a perspective that examines how design decisions can either reinforce or challenge systemic inequalities, and it calls for meaningful inclusion of marginalized communities in the design process. Applying this to B.Stim means actively considering the needs of diverse users in its design and deployment. This includes those from different cultures, socioeconomic backgrounds, genders, and abilities. For example, the headset's adjustability accommodates different head shapes and hair types, ensuring it can be comfortably used by a wide range of people. Instructions and interfaces are kept intuitive and language-inclusive, lowering barriers for users with varying educational levels or technical literacy. This inclusive approach helps avoid biases (such as designing only for a typical male adult user) and strives to empower those who have traditionally been underserved by medical technology.

Another ethical aspect is the responsible and safe deployment of a brain stimulation device. Because B.Stim involves neuromodulation, there are ethical imperatives to ensure it is used appropriately and does no harm. This involves adherence to medical regulations and robust clinical evidence. Prior to widespread use, the device must undergo

rigorous testing for safety and efficacy, and obtain approvals from relevant health authorities. Ethical deployment also means providing clear guidelines to users: since patients will self-administer treatment at home, they must be empowered with knowledge about proper use, potential side effects, and when to seek professional help. The design of B.Stim takes this into account by incorporating user guidance (e.g. intuitive indicators, companion apps or manuals with safety checks) to prevent misuse. It also highlights the importance of informed consent – users should understand the treatment they are engaging in. In this way, B.Stim's rollout would align with strong institutional practices by working within legal and ethical frameworks, and by strengthening trust in medical innovation. Building trust is crucial: patients and clinicians need confidence that the device is not only effective but also ethically designed with the user's well-being at the forefront.

10.3. Environmental Sustainability and the Design for Sustainability Framework

From a sustainability perspective, B.Stim's design process is informed by the Ceschin & Gaziulusoy multi-level Design for Sustainability (DfS) framework, which promotes intervention at multiple levels. From materials to socio-technical systems. At the material and product level, the device is designed using biocompatible and recyclable components, such as non-toxic electrodes and casing plastics, while low-power electronics ensure energy efficiency. The product is intended to be durable and modular, enabling long-term use and easy replacement of worn-out parts. Life-cycle thinking is applied from the outset to allow for disassembly and material recovery at end-of-life.

At the product–service system level, B.Stim adopts a rental-based business model to operationalize circular economy principles. Rather than selling the headset to individual users, the device is rented out for the duration of treatment and then returned to the provider. This system enables centralized maintenance, component replacement, software updates, and eventual refurbishment or recycling. Returned devices can be inspected, cleaned, and upgraded for future use, drastically reducing waste and material demand. This not only ensures that each product is used to its full potential but also promotes economic accessibility, as patients pay for the service rather than the full product. By shifting ownership and responsibility for the product's full life cycle to the provider, this model strengthens the sustainability of the system while aligning with the broader goals of SDG 12 and circular design.

The B.Stim project illustrates how industrial design can serve as a powerful lever for addressing complex societal challenges at the intersection of health, ethics, and sustainability. Through its alignment with key Sustainable Development Goals the project demonstrates a holistic approach to innovation. For example; including health and well-being, economic growth, responsible consumption, and ethical governance. By embedding principles from the Design for Sustainability framework and adopting a rental-based product-service model, B.Stim not only reduces environmental impact but also enhances accessibility and long-term value. Ethical considerations, inclusive design, and user empowerment remain central to its development, ensuring that technological progress is paired with social responsibility. In doing so, B.Stim serves as a case study in responsible innovation, contributing not only to better mental health care, but also to a more equitable and sustainable future.

11 Discussion

The central objective of this thesis is to design B.Stim, a transcranial electrical stimulation (TES) headset that is both user-friendly and personalized for home use in treating depression. This objective arises from the need for an accessible somatic therapy for depression that patients can use independently, bridging the gap between clinical efficacy and everyday usability. B.Stim is designed as a lightweight, portable device, emphasizing a user-centric approach to

overcome practical barriers in home-based treatment. The final design meets the criteria for user-friendliness and home use by incorporating features that simplify operation for laypersons. For instance, the headset uses modular electrodes and intuitive controls so that setup and use are as simple as possible, directly addressing common challenges like correct electrode placement and adherence to therapy protocols. In essence, the device transforms a complex medical procedure into a safe, straightforward home treatment, enabling patients to administer their own TES sessions with confidence.

A key achievement of the project is the successful integration of personalization through a modular electrode design. Depression is a heterogeneous illness, and effective treatment can vary greatly between individuals. Consequently, B.Stim is conceived to allow tailoring of the therapy to each user's needs, physiology, and head size. The final design realizes this by deploying a modular electrode system that grants full freedom in electrode placement. Electrode connection ports are integrated along the entire headset band, enabling users to position electrodes anywhere according to a prescribed stimulation montage. This flexible design fulfills a core usability requirement without compromising the device's simplicity or form. That is to support personalized treatment protocols for different patients. In practice, the user can easily adjust the number, type, and location of electrodes to target specific brain regions as directed by a clinician, something not possible with fixed-position headsets. This modular approach not only accommodates individual anatomical differences and therapeutic targets, but also offers a scalable platform for future enhancements (such as new electrode types or montages). By providing full configurational freedom in a home-use device, B.Stim achieves the desired personalization that is critical for addressing the diverse profiles of depression. This personalized capability is implemented in a manner that remains intuitive.

Equally important, the usability and user experience of B.Stim have been validated through iterative evaluation. Usability testing with representative users confirms that the product concept is fundamentally intuitive, well-structured, and well-received. Participants with no specialized training were able to complete the headset setup, position the electrodes, and navigate the interface with minimal guidance, indicating that the device can indeed be used safely at home by patients. The testing highlighted that users felt confident in operating B.Stim, thanks in part to clear feedback cues (such as the aforementioned magnetic connections and a calming, guided software interface). Notably, the interface was praised for its clarity and reassuring tone, supporting the design goal of reducing user error and anxiety during self-administration. These findings demonstrate that the current user experience works well in practice – users are able to correctly follow the stimulation protocol and reported comfort and trust in the device during use. Minor issues were noted (for example, a need for clearer instructions on sponge electrode preparation and post-session care), but these are relatively straightforward improvements and do not undermine the overall usability. In summary, the testing and validation activities show that B.Stim effectively meets its user-friendliness criteria: it can be operated by a non-expert in a home setting, integrates safety and clarity to build user confidence, and aligns with daily life routines of patients.

11.1. Recommendations for Future Work

While B.Stim successfully demonstrates a viable design direction, further work is recommended to refine the product and prepare it for real-world deployment:

11.1.1. Electronics Development

Involve specialized biomedical engineers or electronics experts in the next development phase to advance the TES circuitry and firmware. The current electronics meet basic functionality for prototype purposes, but expert involvement is needed to ensure medical-grade safety, reliability, and compliance with technical standards. This includes refining current delivery precision, implementing robust safety cut-offs, and integrating features like dosage tracking or remote

monitoring as required for clinical use. Collaboration with experts will help transform the working prototype into a fully engineered system ready for certification and production.

11.1.2. Enhanced Comfort

Continue to improve the ergonomic comfort of the headset so that wearing B.Stim becomes as natural and unobtrusive as wearing a conventional headset or headphones. User feedback indicates that, there is room to optimize the fit, weight distribution, and materials (e.g. cushioning and adjustability) for extended use. Future iterations should explore advanced materials and adjustable form factors that conform to various head shapes and sizes, thereby increasing user compliance. The goal is to match or exceed the comfort level of existing consumer headsets, ensuring that long-term daily use does not cause discomfort or fatigue.

11.1.3. Certification and Market Preparation

Plan for the extensive process of medical certification and market introduction. Transitioning B.Stim from a prototype to a market-ready medical device will require substantial time, testing, and resources. Future efforts should include clinical trials to formally evaluate the efficacy and safety of home-based TES in depression treatment, as well as thorough documentation to satisfy regulatory requirements (such as CE marking in Europe or FDA approval in the US). Additionally, quality management systems need to be established to comply with medical device regulations. It is important to acknowledge that obtaining the necessary medical certifications, scaling up manufacturing, and establishing distribution channels will be a significant undertaking. Early engagement with regulatory experts and strategic planning for fundraising and partnerships will be crucial to navigate this path.

By addressing these areas, the B.Stim project can move from a proven concept toward a commercially viable therapeutic option. Each recommendation builds on the strong foundation laid by this thesis, targeting the remaining gaps between the current prototype and a deployable healthcare product.

11.2. Added value and outlook

This thesis work provides substantial added value to the partnering client (the start-up behind B.Stim) by delivering a validated, human-centered design direction for their product. Prior to this project, the concept of a home-use TES device for depression was largely unproven in terms of user acceptance and practical feasibility. The outcomes of this design research now give the client a concrete and user-validated concept to pursue. The design direction established here is grounded in user research, iterative prototyping, and testing, ensuring that patient needs and experiences remain at the forefront. As a result, the start-up gains not only a tangible prototype but also evidence that the B.Stim approach is intuitive and adaptable for real users, significantly de-risking further development investments. In particular, the modular electrode system and the interface design have been validated as effective solutions to personalization and ease-of-use requirements, which are critical differentiators for the product in the market. This human-centered approach and the insights documented in this thesis serve as a roadmap for the company's next steps. These can go from engineering development to clinical validation, and demonstrating to stakeholders (investors, clinicians, and regulators) that the core concept is sound and responsive to user needs.

In conclusion, the design of B.Stim as presented in this thesis achieves its aim of creating a user-friendly and personalized TES headset for home treatment of depression. The project illustrates how combining clinical goals with empathetic design can yield a device that is technologically functional and truly oriented to the end-user. By empowering patients

with a comfortable, easy-to-use, and adaptable tool, B.Stim has the potential to increase engagement in therapy and improve outcomes in a chronic illness where sustained use is paramount. The work done here lays a strong foundation for future innovation: it confirms the feasibility and appeal of at-home TES, informs the necessary steps to bring such a device to market, and contributes knowledge to the emerging intersection of mental health treatment and consumer-grade medical design. Ultimately, B.Stim stands as a proof-of-concept that depression treatment devices can be both clinically effective and designed for everyday life. This dual achievement is essential for making advanced therapies accessible to those who need them most. The thesis thereby advances the client's mission and adds to the broader discourse on patient-centered design in medical technology, pointing the way toward more personalized and user-empowering solutions in mental health care.

12 AI Usage

Artificial intelligence (AI) was employed during this thesis project as a supportive tool in both the design and writing processes. In the design phase, generative AI was used to assist in the early ideation of product concepts, particularly by visualizing alternative form factors and aesthetic directions that informed subsequent development. In the writing phase, AI tools were utilized to help structure the thesis document, refine phrasing, and improve the clarity and coherence of academic language. This integration of AI served to enhance the creative process and ensure a clear, well-organized final report, while all critical content and design decisions remained grounded in user research and engineering rationale.

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14 Appendix

Appendix A

FEATURE	DIADEEM EEG	FLOW	PLATOWORK
Type of sensors/electrodes	EEG dry sensors with active shielding	non reusable Pads with saline solutoin 22.9cm² (5.4cm diameter)	Sponges with saline solution. Can be rinsed, dried and reused (4x5cm)
Amount of sensors/electrodes	12 sensors	2 electrodes	3 electrodes
Head perimeter	53-61 cm		55-60cm
Integrated sensors	IMU(9 axis): accelerometer, gyroscope magnetometer		
Inputs	Digital input, optical trigger	Digital input	Digital input
Data transmission and range	Bluetooth 2.1 + EDR with 10 meter in direct sight	Bluetooth	Bluetooth range 1-5 meter
Data backup?	Yes, with removable SD card		
Battery	Rechargeable lipo battery	Rechargeable Lipo 3.7V 250mAh	Lipo 3.7V 500mah rechargeable
Weight	headset: 185g amplifier: 122g Total: 307g	110g	187g
Maintenance	Wipes moistened in tap water	Replacement of pads after each session	Replacement of pads after 90 sessions (and rinsing every session)
Water Ingress protection		IP22	IP22
Nominal voltage	3.7		
Nominal power	750 mW		
Battery life	>8h	10 stimulation sessions?	+-7.5h (15 sessions)
Charging time	≤3h	1h	
Charging connection	Barrel plug connector	Micro USB 5V DC	Micro USB 5V 3W
Contact points with head			
Contact point surface	Silicone	ABS	Silicone with structure 
Electrode positioning mechanism	Fixed	Fixed	3 positions
Electrode attachment/ detachment mechanism	Fixed	Fixed	Fixed
Sizing mechanism			
Dimensions	headband: 195 x 175 x 90 mm amplifier: 71 x 71 x 34 mm	185 x 170 x 115 mm	170 x 190 x 210 mm

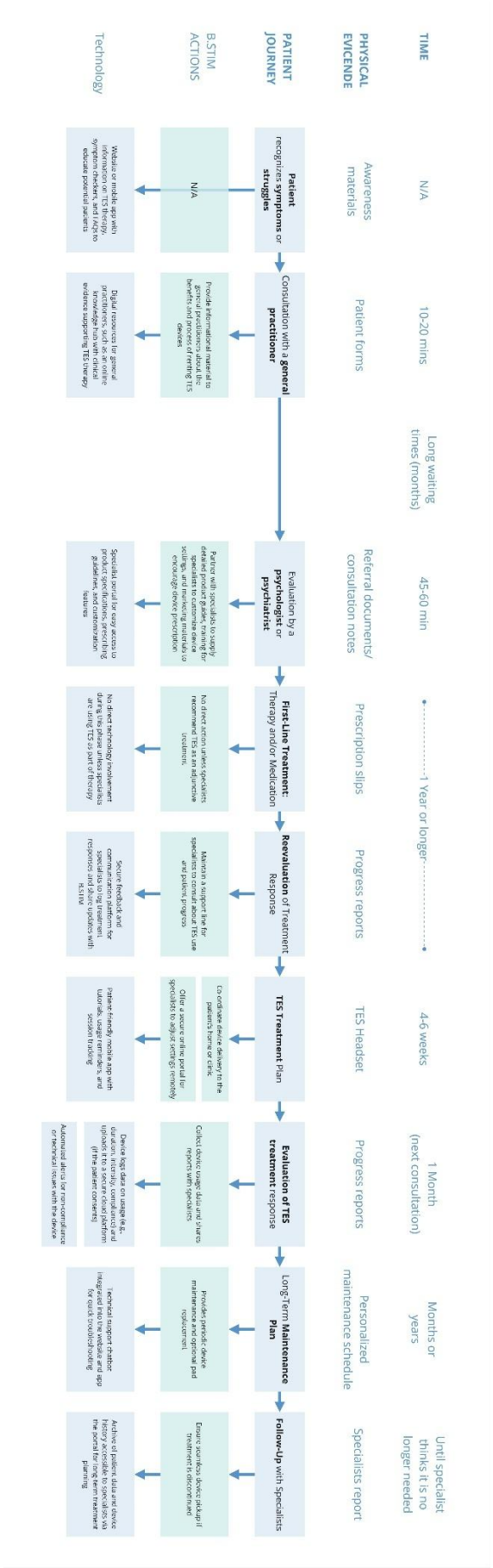
Appendix B

REQUIREMENTS		Applicable for B.Strn?		YES	NO
10. Chemical, physical and biological properties					
10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:					
a)	the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;				
b)	the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;				
c)	the compatibility between the different parts of a device which consists of more than one implantable part:				
d)	the impact of processes on material properties;				
e)	where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;				
f)	the mechanical properties of the materials used, reflecting, where appropriate. matters such as strength. ductility. fracture resistance. wear resistance and fatigue resistance:				
g)	surface properties; and				
h)	the confirmation that the device meets any defined chemical and/orphysical specifications.				
10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.					
10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.					
10.4. Substances					
10.4.1. Design and manufacture of devices Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that:					
	are invasive and come into direct contact with the human body,				
	/re)administer medicines. bodv liquids or other substances. including gases. to/from the bodv. or				
	transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,				
shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:					
a)	substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European				
b)	substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.				
10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances					
a)	an analysis and estimation of potential patient or user exposure to the substance;				
b)	an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;				
c)	argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularlyvulnerable to such substances and/or materials; and				
d)	where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.				
10.4.3. Guidelines on phthalates For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.			Wat is dit?		
10.4.4. Guidelines on other CMR and endocrine-disrupting substances Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.					
10.4.5. Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.					
10.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.					
10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.					
11. Infection and microbial contamination					
11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:					
a)	reduce as far as possible and appropriate the risks from unintendedcuts and pricks, such as needle stick injuries,				
b)	allow easy and safe handling,				
c)	reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and				
d)	prevent microbial contamination of the device or its content such asspecimens or fluids.				
11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.					
11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.					
11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.					
11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.					
11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.					
11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.					
11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.					
12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.					
12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.					
12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.					
13. Devices incorporating materials of biological origin					
13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:					
a)	donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;				
b)	Processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process:				
c)	the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.				

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:		
a)	where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;	
b)	sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to virusesand other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;	
c)	in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.	
13.3. For devices manufactured utilising non -viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.		
14. Construction of devices and interaction with their environment		
14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.		
14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:		
a)	the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	
b)	risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	
c)	the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	
d)	the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	
e)	the risks of accidental ingress of substances into the device;	
f)	the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and	
g)	risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	
14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.		
14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		
14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.		
14.6. Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.		
14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.		
15. Devices with a diagnostic or measuring function		
15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.		
15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).		
16. Protection against radiation		
16.1. General		
a)	Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	
b)	The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	
16.1. Intended radiation		
a)	Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non- ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall bepossible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	
b)	Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.	
16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.		
16.4. Ionising radiation		
a)	Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.	
b)	Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, ifpossible, monitored during treatment.	
c)	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.	
d)	Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.	
17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves		
17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.		
17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.		
17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).		
17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.		
18. Active devices and devices connected to them		
18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.		
18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.		
18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.		
18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.		
18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.		
18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.		
18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.		
18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.		
19. Particular requirements for active implantable devices		
19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:		

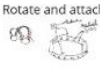
a)	risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,																				
b)	risks connected with medical treatment, in particular those resulting from the use of defibrillators or high- frequency surgical equipment. and																				
c)	risks which may arise where maintenance and calibration are impossible, including: — excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism.																				
19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure																					
a)	if applicable, the compatibility of the devices with the substances they are intended to administer, and																				
b)	the reliability of the source of energy.																				
19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.																					
19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.																					
20. Protection against mechanical and thermal risks																					
20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.																					
20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.																					
20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.																					
20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.																					
20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.																					
20.6 Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.																					
21. Protection against the risks posed to the patient or user by devices supplying energy or substances																					
21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.																					
21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.																					
21.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.																					
22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons																					
22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.																					
22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:																					
	ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,																				
	reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and																				
	reduce as far as possible the risk of error by the intended user in thehandling of the device and, if applicable, in the interpretation of the results.																				
22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:																					
	ßan verify that, at the time of use, the device will perform as intended by the manufacturer, and																				
	if applicable, is warned if the device has failed to provide a valid result.																				

Appendix C


TIME
PHYSICAL EVIDENDE
PATIENT JOURNEY
B.STIM ACTIONS
Technology
N/A
10-20 mins
Long waiting times (months)
45-60 min
1 Year or longer
4-6 weeks
1 Month (next consultation)
Months or years
Until specialist thinks it is no longer needed
Awareness materials
Patient forms
Referral documents/ consultation notes
Prescription slips
Progress reports
TES Headset
Progress reports
Personalized maintenance schedule
Specialists report
Patient recognizes symptoms or struggles
Consultation with a general practitioner
Evaluation by a psychologist or psychiatrist
First-Line Treatment: Therapy and/or Medication
Reevaluation of Treatment Response
TES Treatment Plan
Evaluation of TES treatment response
Long-Term Maintenance Plan
Follow-Up with Specialists
N/A
Provide informational material to general practitioners about the benefits and process of starting TES devices
Partner with specialists to supply detailed product guides, training for specialists, and marketing materials to encourage device prescription
No direct actions unless specialists recommend TES as an adjunctive treatment.
Maintain a support line for specialists to discuss TES use and patient progress
Co-ordinate device delivery to the patient's home or clinic
Offer a secure online portal for specialists to adjust settings remotely
Collect device usage data and share reports with specialists
Provide periodic device maintenance and replacement
Ensure seamless device pickup if treatment is discontinued
Website or mobile app with information on TES therapy, symptom checkers, and FAQs to educate potential patients
Digital resources for general practitioners, such as an online knowledge hub with clinical evidence supporting TES therapy
Specialist portal for easy access to product specifications, prescribing guidelines, and customization features
No direct technology involvement during this phase unless specialists are using TES as part of therapy
Secure feedback and communication system for specialists to log treatment responses and share updates with B.STIM
Patient-friendly mobile app with tutorials, usage reminders, and session tracking
Device logs data on usage (e.g., duration, intensity, compliance) and uploads it to a secure cloud platform (if the patient consents)
Automated alerts for non-compliance or technical issues with the device
Technical support chatbox integrated into the website and app for quick troubleshooting
Archive of patient data and device history accessible to specialists via the portal for long-term treatment planning

Appendix D

New table

FEATURE	IDEAS								
Type of electrodes	Dry electrode	non reusable Pads with saline solution 22.9cm² (5.4cm diameter)	Sponges with saline solution. Can be rinsed, dried and reused (4x5cm)						
Amount of electrodes	2	3	4	5					
Head perimeter	53-61 cm (by anthropometry)	55-60cm							
Integrated sensors	IMU(9 axis): (accelerometer, gyroscope magnetometer)	none	Optical sensor						
Inputs	Digital input		Physical input						
Data transmission and range	Bluetooth	Wifi	Wired						
Data backup?	Yes, with removable SD card	None	Cloud						
Battery	Rechargeable lipo battery inside headset	Rechargeable lipo battery, swappable	Rechargeable Li-Ion	Alkaline					
Weight	+-100g	+-150g	+-200g	+-250g					
Maintenance	Wipes moistened in tap water	Replacement of pads after each session	Replacement of pads after # amount of sessions	Rinsing under tap water					
Water Ingress protection	None	IP22 (Condensation protection)	IP67 (waterproof)	IP55 (sweatproof)					
Nominal voltage	?								
Nominal power	?								
Battery life	30min (enough for 1 session)	1h	2h	3h	as much as is possible with fitting battery				
Charging time	≤3h	1h	As fast as possible						
Charging connection	Barrel plug connector	Micro USB	USB C	USB					
Contact points with head	2	3	4	Bigger contact surface					
Contact point surface	Silicone	ABS	Silicone with structure	Foam pad					
Electrode positioning mechanism	Fixed	3 positions	Rotating system 	Rotate and attach 	Full head coverage and attach 		Coordinate system 		
Electrode attachment/ detachment mechanism	Fixed	Detachable							
Sizing mechanism	None	Elastic	Headphone strap mechanism	Helmet tightening mechanism					
Dimensions	195 x 175 x 90 mm	185 x 170 x 115 mm	170 x 190 x 210 mm	TBD					
User interface controls	Button controls on device	app interface	audio	Basic remote	remote with screen				

Appendix E

WEIGHTED DECISION MATRIX

Feature:		Type of sensors/electrodes			
Criteria	Weight	Dry electrodes	Pads with saline solution	Sponges with saline solution	
User comfort	4	5	4	4	
Ease of use	3	5	2	2	
Customizability	4				
Safety	3	4	5	5	
Battery life	2				
Durability and maintenance	1	5	2	2	
Connectivity & feedback	2				
	Total:	42	39	39	0

Feature:		Amount of electrodes				
Criteria	Weight	2	3	4	5	
User comfort	4	5	5	5	5	5
Ease of use	3	5	4	3	2	2
Customizability	4	2	3	4	5	5
Safety	3					
Battery life	2	5	4	3	2	2
Durability and maintenance	1	5	4	3	2	2
Connectivity & feedback	2					
	Total:	58	56	54	52	52

Feature:		Integrated Sensors			
Criteria	Weight	IMU	None	Optical sensor	
User comfort	4				
Ease of use	3	5	2	4	
Customizability	4				
Safety	3	5	2	4	
Battery life	2	5	5	5	
Durability and maintenance	1	5	5	5	
Connectivity & feedback	2	5	2	5	
	Total:	45	33	35	0

Feature:		Inputs			
Criteria	Weight	Digital input	Physical input		
User comfort	4	5	4		
Ease of use	3	5	4		
Customizability	4				
Safety	3				
Battery life	2	5	5		
Durability and maintenance	1	5	5		
Connectivity & feedback	2	5	4		
	Total:	50	49	0	0

Feature:		Data transmission and ranie				
Criteria	Weight	Bluetooth	Wifi	Wired	IR	
User comfort	4	5	5	5	5	5
Ease of use	3	5	4	5	4	4
Customizability	4					
Safety	3	5	5	5	5	5
Battery life	2	4	4	5	4	4
Durability and maintenance	1	5	5	4	5	5
Connectivity & feedback	2					
	Total:	93	48	48	48	48

Feature:		Data backup			
Criteria	Weight	With removable SD Card	None	Cloud	
User comfort	4	2	1	5	
Ease of use	3	2	1	5	
Customizability	4				
Safety	3	5	1	1	
Battery life	2	5	5	1	
Durability and maintenance	1	4	5	4	
Connectivity & feedback	2	5	1	3	
	Total:	53	27	58	0

Feature:		Battery			
Criteria	Weight	Rechargeable Lipo	Rechargeable and swappable LiPO	Alkaline	
User comfort	4	5	5	3	
Ease of use	3	5	5	3	
Customizability	4				
Safety	3	5	3	3	
Battery life	2	5	5	1	
Durability and maintenance	1	4	5	2	
Connectivity & feedback	2				
	Total:	64	59	34	0

Feature:		Weight			
Criteria	Weight	100-150g	200-250g		
User comfort	4	5	3		
Ease of use	3	5	5		
Customizability	4				
Safety	3				
Battery life	2				
Durability and maintenance	1	1	1		
Connectivity & feedback	2				
	Total:	24	32	0	0

Feature:		Maintenance				
Criteria	Weight	Wipes moistened in tap wat	Replacement of pads after each session	Replacement of pads after 4 sess	Rinsing under water	
User comfort	4	5	1	4	5	5
Ease of use	3	5	1	4	5	5
Customizability	4					
Safety	3	4	5	2	4	4
Battery life	2					
Durability and maintenance	1	5	3	5	3	3
Connectivity & feedback	2					
	Total:	62	25	39	59	59

Feature:		Water ingress protection				
Criteria	Weight	None	IP22	IP67	IP55	
User comfort	4					
Ease of use	3					
Customizability	4					
Safety	3	1	2	4	3	3
Battery life	2					
Durability and maintenance	1	1	2	4	3	3
Connectivity & feedback	2					
	Total:	4	8	16	12	12

Feature:		Battery life				
Criteria	Weight	30 min (1 session)	1 hour	2 hours	As much as possible with fitting battery	
User comfort	4	2	3	4	5	5
Ease of use	3	2	3	4	5	5
Customizability	4					
Safety	3					
Battery life	2	2	3	4	5	5
Durability and maintenance	1					
Connectivity & feedback	2					
	Total:	18	27	36	45	45

Feature:		Contact point surface				
Criteria	Weight	Silicone	ABS	Silicone with structure	Foam pad	
User comfort	4	4	3	5	4	4
Ease of use	3	5	4	5	5	5
Customizability	4					
Safety	3	5	5	5	2	2
Battery life	2					
Durability and maintenance	1	5	5	4	2	2
Connectivity & feedback	2					
	Total:	51	44	54	33	33

Feature:		User interface controls				
Criteria	Weight	Button controls	App	Audio	Remote	Remote with screen
User comfort	4	3	5	3	4	5
Ease of use	3	3	5	3	4	5
Customizability	4	1	5	1	1	5
Safety	3					
Battery life	2	5	5	1	1	1
Durability and maintenance	1	5	5	5	1	1
Connectivity & feedback	2	5	1	1	1	1
	Total:	50	72	34	37	60

Appendix F

New table

FEATURE	IDEAS								
Type of electrodes	Dry electrode	non reusable Pads with saline solution 22.9cm² (5.4cm diameter)	Sponges with saline solution. Can be rinsed, dried and reused (4x5cm)						
Amount of electrodes	2	3	4	5					
Head perimeter	53-61 cm (by anthropometry)	55-60cm							
Integrated sensors	IMU(9 axis): (accelerometer, gyroscope magnetometer)	none	Optical sensor						
Inputs	Digital input		Physical input						
Data transmission and range	Bluetooth	Wifi	Wired	IR					
Data backup?	Yes, with removable SD card	None	Cloud						
Battery	Rechargeable lipo battery inside headset	Rechargeable lipo battery, swappable	Rechargeable Li-Ion	Alkaline					
Weight	+-100g	+-150g	+-200g	+-250g					
Maintenance	Wipes moistened in tap water	Replacement of pads after each session	Replacement of pads after # amount of sessions	Rinsing under tap water					
Water Ingress protection	None	IP22 (Condensation protection)	IP67 (waterproof)	IP55 (sweatproof)					
Nominal voltage	?								
Nominal power	?								
Battery life	30min (enough for 1 session)	1h	2h	3h	as much as is possible with fitting battery				
Charging time	≤3h	1h	As fast as possible						
Charging connection	Barrel plug connector	Micro USB	USB C	USB					
Contact points with head	2	3	4	Bigger contact surface					
Contact point surface	Silicone	ABS	Silicone with structure	Foam pad					
Electrode positioning mechanism	Fixed	3 positions	Rotating system 	Rotate and attach 	Full head coverage and attach 		Coordinate system 		
Electrode attachment/ detachment mechanism	Fixed	Click in place	Slide in place	Screw in place					
Sizing mechanism	None	Elastic	Headphone strap mechanism	Helmet tightening mechanism					
Dimensions	195 x 175 x 90 mm	185 x 170 x 115 mm	170 x 190 x 210 mm	TBD					
User interface controls	Button controls on device	app interface	audio	Basic remote	remote with screen				

Appendix G

9:41

Back

Tilt your head to the right

Tilt your head to the right and press the button while tilting your head to the right

I am tilting my head to the right

Cancel session

More info — Settings

9:41

Back

Are you sure you want to cancel the session?

Yes I'm sure

Continue session

More info — Settings

9:41

Back

Charge device

Place the device on the charging base to make sure you are ready for the next session tomorrow.

Done

More info — Settings

9:41

Back

Post session checkup

To get a good impression of the impact of this treatment a post session checkup is done, answer the questions as truthfully as possible.

Done

More info — Settings

9:41

Back

Fill saline bath till 2nd line

Fill the bath with saline solution until the first line

Done

Cancel session

More info — Settings

9:41

Back

Wait for impedance check to be completed

An impedance check is done to make sure the electrodes have a perfect connection

Done

Cancel session

More info — Settings

9:41

Back

Wait for impedance check to be completed

An impedance check is done to make sure the electrodes have a perfect connection

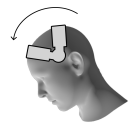
Wait

Cancel session

More info — Settings

9:41

Back



Look down

Look down and press the button while looking down

I am looking down

Cancel session

More info — Settings

9:41

Back

Rotate small extention arm electrode to setting 4

The different settings are indicated around the casing of the electrode connector, rotate untill the indicator lines up with the number or inbetween 2 numbers

Done

Cancel session

More info — Settings

9:41

Back

Rotate medium extention arm electrode to setting 5

The different settings are indicated around the casing of the electrode connector, rotate untill the indicator lines up with the number or inbetween 2 numbers

Done

Cancel session

More info — Settings

9:41

Session | Agenda

Today's session is completed

More info — Settings

9:41

Session is complete, Well done!

Continue

More info — Settings

9:41

Back

How is your mood?

Very bad | Bad | Neutral | Good | Very good

Did you experience any pain during the session?

Yes | No

Did you experience any tingling during the session?

Yes | No

Done

More info | Settings

9:41

Back

Clean device

Clean the stimulation device if needed. Rinse with water and make sure you wipe it dry before going to the next step.

Done

More info | Settings

9:41

Back

Connect device

Go to bluetooth and connect the device
Wait for the LED to stop blinking

Done

Cancel session

More info | Settings

9:41

Back

Detach electrodes and remove sponges

Detach the electrodes from the connection slots in the headset band.
Slide the sponges from the rubber electrodes.

Done

More info | Settings

9:41

Back

Slide the wet sponges over the rubber electrodes

Slide the soaked sponges over the previously selected electrodes, make sure they sit snug and cover the whole electrode

Done

Cancel session

More info | Settings

9:41

Back

Power on the device

Hold the power button for 2 seconds and wait for the status-LED to blink

Done

Cancel session

More info | Settings

9:41

Back

Put the device on your head

Put the black side of the headset to the front. Pay attention to indications on the screen for correct positioning

Done

Cancel session

More info | Settings

9:41

Back

You are ready to start your session!

Sit back and relax, you will be starting a 20 minute session.

If you cancel while it is still running the session will fail so make sure you have time to complete it.

Start session

Cancel session

More info | Settings

9:41

Session | Agenda

Start today's session

More info | Settings

9:41

× Sign Up Login

Name

Email

Password Show

Sign Up

Forgot your password?

Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M
123 space Go

9:41

Back

Let the sponges soak

Place the sponges of the electrodes in the saline solution bath for 1 minute

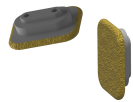
Done

Cancel session

More info | Settings

9:41

Back



Take electrodes:

1x Standard electrode

Take 1 standard type electrode, this electrode has no extention arm

Done

Cancel session

More info | Settings

9:41

Back

You're done for today, well done!

Back to menu

More info — Settings

9:41

1 : 10

80% Done

Session duration

Cancel session

More info — Settings

9:41

Back

Place small extention arm electrode on connection port G

Port G is indicated with and engraved letter G above

Done

Cancel session

More info — Settings

9:41

Remove device from head

Take the device off and follow further instructions to finish session

Done

More info — Settings

9:41

Back

Rinse electrodes sponges and let them airdry

Rinse the electrodes with water and let them dry on the designated place on the device stand.

Done

More info — Settings

9:41

Back

Place regular electrode on connection port L

Port L is indicated with and engraved letter L above

Done

Cancel session

More info — Settings

9:41

Back

Take electrodes: 1x small extention arm electrode

Take 1 small-size extention arm electrode electrode

Done

Cancel session

More info — Settings

9:41

Back

Take electrodes: 1x medium extention arm electrode

Take 1 medium-size extention arm electrode electrode

Done

Cancel session

More info — Settings

9:41

Back

Place medium extention arm electrode on connection port P

Port P is indicated with and engraved letter P above

Done

Cancel session

More info — Settings

Appendix H

User Test Protocol – B.Stim Headset

1. General Info

- **Test Name**: B.Stim Integrated Usability Test
- **Objective**: To evaluate the usability, intuitiveness, and overall user experience of the B.Stim headset, modular electrodes, and app interface during a simulated TES session.
- **Participants**: Collegues of Stakeholder Laís, lay users
- **Facilitator**: Rune Vandekerckhove, student industrial design
- **Location**: UZ Ghent, home of the lay users
- **Materials**:
    - Functional prototype of the B.Stim headset
    - Sponge electrodes with sleeves and markings
    - Saltwater bottle
    - Water basin with markings
    - Figma prototype on tablet or phone
    - Observation notes
    - Consent forms
    - Pre and post session question list

2. Test Goals

- Assess how intuitively users can navigate the UI and follow instructions.
- Observe how well users can mount and adjust the headset and electrodes.
- Test whether the headset can be set up correctly with the app instructions
- Test whether users understand feedback from the app (e.g., fit warnings, impedance checks, session start).
- Identify any sources of confusion, discomfort, or hesitation during the process.

3. Test Scenario

You are a first-time user of the B.Stim device, you get the first guided session info from the medical professional and nog you are preparing to use it at home. You will follow the app instructions to:

1. Set up your account (if not already created)
2. Prepare the sponge electrodes
3. Attach the electrodes to the headset in the correct position
4. Put on the headset and adjust it for comfort and fit
5. Let the app check fit/impedance (simulated if needed)
6. Start a mock stimulation session
7. Complete the session and clean/store components

4. Step-by-Step Tasks for Participant

Step	Task Description	Success Criteria
1	Open the app and follow the onboarding steps	Completes account setup without help
2	Prepare electrodes using sponge sleeves and salt solution	Electrodes are correctly soaked and installed
3	Attach electrodes to the headset as instructed	Snap connectors used correctly; positioned as shown
4	Place and adjust the headset	Headset fits snugly and comfortably
5	Wait for/check system fit & status in UI	Understands and reacts appropriately to system messages
6	Start the (mock) stimulation	Starts session without confusion
7	End session and remove headset	Completes wrap-up steps correctly
8	Clean and store all components	Stores sponges, dries parts as instructed

The users are only given a QR code that opens the app for guidance and the parts of the BStim device. The rest of the tasks are given through the UI

5. Data Collection

- **Observation Sheet** (note where help is needed, time per step, mistakes)
- **Think-Aloud Protocol** (ask participant to narrate their thoughts)
- **Post-Test Interview**

Appendix I

Objective	Design Requirement	Cause/Problem/Context	Fulfilled / Partially fulfilled/ Pending	Justification
Hygiene and Cleanability	Waterproof and water-resistant materials	Renting of B.Stim	Fulfilled	materials have been chosen to be waterproof or water-resistant
Hygiene and Cleanability	Switchable parts/electrodes	Detachable and replaceable parts like electrodes or pads for personal hygiene	Fulfilled	The modular electrodes make it easy to switch and clean the parts
Hygiene and Cleanability	Waterproofing/resistance for cleaning	Waterproofing/resistance for cleaning	Partially fulfilled	Design needs more detailed waterproofing and testing to fulfill this step
User Experience	Customizability		Fulfilled	The user experience is designed to be as customizable as possible while maintaining compliance with medical protocols.
User Experience	Smooth surfaces with no hard-to-clean crevices		Fulfilled	During the design attention was paid to make an easily cleanable device
User Experience	Have a good fit for every head size		Partially fulfilled	The device is adaptable to different head sizes and constructed from flexible materials; however, further adjustments are needed to enhance comfort in future iterations.
User Experience	As much freedom as possible for the placement of the electrodes		Fulfilled	By incorporating the modular electrode system and extension arm electrodes, the headset can cover the entire scalp, providing maximum flexibility in stimulation placement.
User Experience	Adjustable straps or sizing mechanisms to fit various head shapes and sizes		Partilly fulfilled	The sizing mechanisms allow the headset to fit a variety of head shapes, but further changes are needed to improve overall adjustability in future versions.
User Experience	Adjustable mechanism for placement of electrodes	Possibility to add/remove electrodes	Fulfilled	The modular electrodes provide an adjustable mechanism for placement of electrodes
Electronics	Powered by battery		Fulfilled	The device is powered by a 3.7V lipo battery
Electronics	Headset is used correctly by every user		Partially fulfilled	The usertests proved that the current UI

				provides a good guide for the users during a session and the headset is user correctly. However to be able to say that this step is completely fullfilled, a lot more testing needs to be done in the future.
Electronics	Intuitive design		Partially fulfilled	Same as item above
Electronics	Clear instructions for setup and use		Partially fulfilled	Same as item above
Electronics	Safety protocols to prevent misuse		Partially fulfilled	For now the known problems are prevented with safety protocols in the app but to get the device to market a lot more safety protocols will need to be implemented.
Electronics	Facilitate repairs	Key components (e.g., electrodes, straps, or pads) should be easily replaceable for reuse and maintenance	Pending	Because the electronics design is not completely finished, it is not yet possible to facilitate repairs but this needs to be kept in mind for the future.
Electronics	Facilitate replacement		Pending	Because the electronics design is not completely finished, it is not yet possible to facilitate replacement but this needs to be kept in mind for the future.
Portability	Lightweight and compact design		Fulfilled	The design is lightweight and folds almost fully closed.
Portability	Rechargeable battery to eliminate reliance on constant power sources		Fulfilled	The design implements a rechargeable battery
Portability	Good rental logistics		Pending	The full design of the business model is out of the scope of this thesis.
Portability	Durable, secure packaging for shipping between rentals		Pending	The packaging design is out of the scope of this thesis.
Data Tracking	Erasing all data between rentals		Pending	The erasing of the data had to be done in the software design and this is out of the scope of this thesis.
Electrodes	no visible Wires		Fulfilled	There are no exposed wires in the design, everything is wired inside the components

Electrodes	Rechargeable		Fulfilled	The electrodes get their power from the rechargeable battery of the device
Electrodes	Indicator for battery level		Fulfilled	A battery level indication can be seen in the UI of the application
Electrodes	Method for applying electrodes as sustainable as possible		Partially fulfilled	For now the most sustainable way is to work with rubber/silicone electrodes placed in a reusable sponge, but these sponges don't last forever.
Electrodes	Good impedance		Partially fulfilled	A impedance checking system is implemented in the electronics to ensure a good impedance during stimulation. This still needs to be worked out in detail but this is out of the scope of this thesis.

Appendix J

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Modular electrodes	During session	Electrode sponge dries out (high impedance)	User fails to adequately wet sponge; extended use dries it	Poor conduction – current pathway becomes resistive or open, causing ineffective stimulation or hot spots	Skin irritation/burn; therapy under-dose (depression not treated)	4	3	12	**Design:** Constant-current source (LT3092) maintains stable output despite impedance changes. **Protective:** Impedance monitoring injects a test current and halts stimulation if contact is poor; app instructs user to re-wet electrodes.	1	1	1	No	Yes (soak pads)	Impedance safety feature integration was verified conceptually – it reduces risk of ineffective or harmful stimulation (design review). Initial supervised sessions ensure users properly prepare electrodes.
	During session	Electrode module detaches or loses contact	Insecure seating in headband slot; sudden movement or worn connector	Open circuit or intermittent contact – stimulation stops unexpectedly or fluctuates, potentially startling user	Therapy interruption (missed dose); transient shock/buzz sensation on reconnection	3	2	6	**Design:** Spring-loaded pogo-pin connectors maintain contact even if module is not optimally seated. Headset frame provides constant gentle pressure to keep electrodes in place. **Protective:** Impedance check stops current on loss of contact, preventing sudden surges; user instructed to perform a "shake test" (head tilt) to confirm secure fit.	2	1	2	No	Yes (fit check)	Prototype testing of Concept 2 revealed contact consistency issues, which were addressed by the modular electrode design (pogo pins and elastic pressure). Usability checks (tilt head test) are built into the session startup to verify secure contact.
	Setup (placement)	Electrode placed at wrong position/orientation	User error in following placement instructions (e.g. swaps anode/cathode or wrong head location)	Stimulation delivered to incorrect brain region or reversed montage – reduced efficacy or unintended effects	Ineffective treatment (no clinical improvement; possible suboptimal stimulation effect)	4	2	8	**Design:** Modular slot system with clearly defined positions on bands to guide placement. **Protective:** First session is supervised by a professional who teaches correct electrode positioning. The mobile app provides visual/auditory cues and confirms when electrodes are in the correct slots. Clear labeling (numbers for orientation and letters for placement)	2	1	2	No	Yes (training & app)	Interviews identified inaccurate placement as a threat without proper guidance. This informed the inclusion of app-driven placement guidance and training. During the initial guided use, correct electrode placement was ensured and user confidence improved.
	During use (extended arm electrode)	Extended electrode arm fails to reach/maintain position	Mechanical joint of arm slips or rotary contact (slip ring) fails after wear or mis-adjustment	Electrode cannot be positioned at target area or loses electrical connection when arm rotates, limiting therapy to that site	Incomplete stimulation of intended area (reduced clinical effect); user frustration adjusting device	3	2	6	**Design:** Rotating arm includes a rated slip ring that provides continuous electrical contact through all angles, preventing wire twisting or disconnection. Arm hinge designed with sufficient friction/tension to hold the electrode in place once positioned (no free flop in normal use). **Protective:** If an extended electrode fails, therapy can still continue with alternate electrode configuration (spare standard electrode provided). Rental maintenance replaces any worn or loose arm components.	2	1	2	No	Possibly (alternate electrode)	The modular electrode concept was developed to improve placement flexibility. Any mechanical weakness would be caught during rental inspection and addressed (replacement of worn parts).
	Prolonged use / multi-user	Electrode causes skin irritation or infection	Electrode pad material not sufficiently biocompatible or is re-used without proper hygiene; high current density due to small/electrode wear	Skin redness or burns under electrode; risk of infection if skin is broken or if a contaminated sponge is reused on another user	Dermal injury (rash, burn) or infection on scalp	3	2	6	**Design:** Electrodes use medically proven sponge materials from reputable suppliers (Neuroelectrics/Soterix/...) and all materials are biocompatible and non-toxic. Electrode size is chosen to keep current density within safe limits. **Protective:** Sponges are single-patient use (replaced for each rental) and cleaning/disinfection protocols are enforced for any reusable electrode parts. The app and manual instruct users on proper electrode care (cleaning skin, using saline as directed).	3	1	3	No	Yes (hygiene instructions)	Material selection and biocompatibility testing ensure no toxic or allergenic components. Any risk of skin irritation is further mitigated by design input from clinical benchmarks and by replacing consumable pads between users. No adverse skin reactions were noted during initial test fittings (expert feedback confirmed comfort).

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Foldable Dual-headband frame & Hinge	Donning/storage	Central hinge breaks or loosens	Repeated folding stresses a weak hinge design (early narrow hinge); material fatigue or user dropping the device	Headset bands detach or wobble – improper electrode alignment and device instability; pieces could pinch skin when breaking	Minor pinching/cut; device unusable until repaired (therapy interruption)	3	2	6	**Design:** Hinge redesigned with increased width and durable material to improve mechanical strength. Folding angle limited to 180° to prevent over-rotation. **Protective:** Prototype testing identified the hinge weakness early, informing design corrections before final build. The final central module was simplified (from 3 parts to 2) to reduce stress points. Rental program can swap out devices that show hinge wear.	2	1	2	No	No (design fix)	The 3D-printed prototype revealed the hinge area as a critical improvement point. In the next iteration the hinge was strengthened and validated for fit and function (parts fit precisely in prototype, confirming design assumptions). No hinge fractures occurred in subsequent handling tests, indicating the redesign's effectiveness.
	Folding/unfolding	Hinge rotation pinches user (finger or hair)	User's finger or hair caught in the rotating joint while adjusting or collapsing the headset	Pinch injury or hair tug – sudden pain or minor injury during handling	Minor injury (skin pinch, bruised finger, hair pulled)	2	2	4	**Design:** Hinge mechanism enclosed or with smooth gaps to minimize pinch points (design requirement to reduce mechanical risks). Silicone pads cover interior surfaces, avoiding exposed moving parts. **Protective:** User instructions advise to remove the headset before folding for storage. Hair is kept clear of the joint during fitting (noted in training).	2	1	2	No	Yes (caution when adjusting)	Safety requirements were defined to *"minimize mechanical risks from movement/parts"*. The final prototype had no sharp edges or very exposed pinch gaps, and no pinch incidents were reported during user fitting trials (participants handled the device without injury in usability tests).
	Wearing (fit)	Frame does not fit securely (improper shape/size)	Headset shape or size range does not match user's head (initial CAD was slightly too large); user head circumference outside design range	Loose fit causes wobbling or sliding – electrodes lose contact when user moves; or too tight fit causes discomfort/headache	Poor contact leads to ineffective stimulation; if overly tight, user pain or unwillingness to wear device	4	2	8	**Design:** Headband geometry refined with anthropometric data for accurate fit. Adjustable sizing mechanism (see next section) covers 5th–95th percentile head sizes. Silicone padding and planned semi-flexible band provide gentle, elastic pressure for stability. **Protective:** Physical prototype testing exposed sizing errors early, allowing correction before final production. Users are instructed to adjust for a snug fit and verify by mild head movements.	2	1	2	No	Yes (fit guidance)	The initial 3D print validation revealed a slight sizing mismatch, prompting an immediate CAD adjustment to improve anatomical accuracy. The refined design achieved a secure yet comfortable fit in later evaluations (Concept 3 was rated highest in comfort/stability by users). No slippage was observed during movement tasks in usability tests, confirming adequate fit.
	Normal use (wearing)	Frame or module cracks under stress (durability issue)	Impact from dropping the device, or long-term material fatigue (e.g. repeated flexing of bands)	Structural failure – could result in sharp edges or loss of structural support for electrodes	Minor cuts if cracked plastic exposes sharp edge; device becomes non-functional (treatment disruption)	3	2	6	**Design:** Robust materials and sufficient wall thickness chosen for structural parts; design for manufacturability includes stress-tested part geometry. Elastic elements (in future design) will absorb shock better than rigid parts. **Protective:** Rental maintenance checks for cracks and replaces any compromised parts (easy replacement design).	2	1	2	No	No (intrinsic)	The CAD model was updated with production-suitable wall thicknesses and part separations to enhance durability. Bench tests of the printed prototype (fitting and moderate bending) showed no cracking, validating the material and geometry choices. The design requirements call for **resistance to degradation and environmental effects**.
	Wearing with accessories	Interference with user's glasses or other gear	Headset bands or electrodes conflict with eyeglasses or hearing aids (Concept 1 had front band blocking glasses)	User cannot wear device properly with their eyeglasses on, or experiences discomfort/poor electrode positioning if they remove glasses	User dissatisfaction or inability to use device as prescribed (especially if vision is needed during session)	2	3	6	**Design:** Final design uses a dual-band concept that avoids excessive front strapping, leaving room around ears for glasses (simpler form than Concept 1). Bands contour above the ears similar to headphone style for compatibility. **Protective:** User guidance suggests adjusting position slightly to accommodate eyewear if needed. Early concept feedback on glasses compatibility was incorporated to ensure the final concept doesn't impede common accessories.	2	1	2	No	Yes (usage tip)	Concept 1's complexity caused *"compatibility issues with glasses"*, which was noted as a weakness. The chosen Concept 3 has a cleaner, minimal band placement, and stakeholders confirmed it is more compatible with eyewear (no testers reported glasses interference with the final design in feedback sessions). This aligns with the ergonomic goal of *intuitive, unobtrusive design* .

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Headband connection slots	Setup (module attachment)	Electrode module not securely latched in track	User fails to fully insert or module locking feature wears down	Module dislodges during treatment – electrical disconnect or shifting contact location	No stimulation at intended site (therapy interruption); could startle user if it snaps out	3	3	9	**Design:** Universal slot connectors are engineered for a snug fit – tolerances validated via prototyping to ensure secure coupling. A tactile/audible "click" by magnet connection confirms placement. **Protective:** Pogo-pin connectors still maintain electrical contact even if the module is not perfectly aligned, reducing likelihood of sudden loss. Users are instructed to check that each electrode module is firmly seated before starting (setup checklist in app).	2	1	2	No	Yes (check module engagement)	Physical assembly tests showed the modular components fit together precisely in the printed prototype, indicating that the connector design is sound. During usability evaluations, participants were able to attach and reposition electrodes without modules falling off (no detachment incidents reported). The spring-loaded connector design inherently keeps the module engaged under mild disturbances.
	Multi-session use	Connector corrosion or wear over time	Saline solution exposure corrodes metal contacts; repeated insertions wear spring pins	Increased contact resistance or intermittent connectivity – could lead to higher impedance or unexpected dropouts	Suboptimal current delivery (possible under-dose) or session abort if contact is lost	3	2	6	**Design:** Contacts are gold-plated and corrosion-resistant; overall assembly is water-resistant to tolerate saline and cleaning. **Protective:** Components like electrodes/pins are designated as wear-prone and replaced periodically (e.g. new electrode kits for each rental, maintenance swaps worn connectors). Device should be dried after use; cleaning instructions provided to prevent salt buildup.	2	1	2	No	Yes (maintenance & cleaning)	The design requirements emphasize materials that **"withstand frequent cleaning and disinfection"**, with **"no hard-to-clean crevices"**, ensuring connectors can be kept clean. The rental model includes a plan for **periodic replacement of wear-prone parts** like electrodes and connectors. No significant corrosion was observed in the short-term lab tests, and the choice of plated pogo pins (rated 3A, gold-plated) provides confidence in long-term conductivity.
	Setup (configuration)	Wrong electrode type or incomplete set used	User inserts an incorrect module (e.g., uses two anodes or misses the return electrode) due to confusion or missing part	Electrical circuit incomplete or improper – stimulation may not start or current concentrates on one electrode	No current flow (session failure) or uneven current distribution (risk of hotspot on one electrode)	4	1	4	**Design:** All electrode modules share a universal connection, preventing truly "wrong" parts (any module will connect). However, correct pairs must be used. **Protective:** The app explicitly shows which electrodes (and how many) are needed for the chosen montage. It will not start the session unless the system detects both an anode and cathode in place (impedance check ensures a complete circuit). Spare electrodes are included in the kit in case one is missing or non-functional.	1	1	1	No	Yes (on-screen prompts)	The guided setup workflow in the app addresses this risk: it instructs the user on **preparing the correct electrodes and their placement**. If an electrode is missing or not making contact, the impedance self-check will prevent the session from starting, as documented in the design (stimulation only proceeds when proper electrode-skin contact is established). This ensures users cannot unknowingly run a session with an incomplete configuration.
	Long-term use	Headband electrode track cracks or deforms	Repeated insertion/removal or stress (bending the band) causes plastic track or slot to break	Electrode can no longer be attached at that location; device loses some placement options or becomes unusable until fixed	Unable to deliver therapy at intended positions; potential delay in treatment if repair needed	3	2	6	**Design:** The headband is made of durable (potentially flexible) material to withstand insertion forces. Slot geometry was optimized in CAD to minimize stress concentrations. **Protective:** If a track does break, the rental service keeps spare headband components and inspects for any cracks between users. Users are advised not to force electrodes improperly (clear insertion instructions).	2	1	2	No	Yes (proper handling)	The second CAD iteration explicitly targeted improved robustness of the headband and its features. The parts were designed for manufacturability and strength, and the prototype evaluation confirmed the assembly could handle component insertion without breaking. Maintenance logs (simulated in the service blueprint) include checking track integrity, aligning with the requirement that **key components be replaceable for maintenance**.
	Setup/operation	Electrode connected to wrong slot (mispositioned along track)	User inserts the electrode module in a slot that is not intended per the protocol (e.g., one position off) due to unclear markings	Stimulation delivered to an off-target location (e.g., slightly wrong brain region), potentially reducing treatment efficacy	Diminished clinical effect (slower or no improvement in condition due to suboptimal targeting)	3	3	9	**Design:** Connection slots are distributed along the band with identifiable markers (numbering or landmarks) to guide correct placement. The modular electrodes were introduced to **increase configurational flexibility without losing guidance**. **Protective:** The app interface instructs exactly which slot positions to use (e.g., "insert sponge electrode at position F") and uses the initial training session to familiarize the user with locating the correct slots. Any significant misplacement would be noticed by the impedance check or by the professional during the first supervised setup.	2	1	2	No	Yes (slot labeling & training)	Concept 3's one noted weakness was **"limited electrode placement freedom... may restrict effectiveness if placement cannot be adapted"**. The solution was to implement a **modular electrode system** with clear positional indexing. In practice, users in the trial were able to follow app placement instructions accurately when visual cues were provided, and expert supervision during the first use confirmed that clear slot markings prevented major placement errors.

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)

headband sizing mechanism/ Adjustable fit system	During session (movement)	Sizing mechanism slips, headset loosens	Friction-based adjuster not tightened enough or gradual slip under motion; possible wear of friction pad	Headset expands during use – becomes loose on head, electrodes lose proper contact or shift position	Interrupted stimulation (open circuit if contact lost); need to readjust mid-session (inconvenience)	3	3	9	**Design:** The friction sizing mechanism was tested to hold position reliably (selected after evaluation showed comparable performance to BOA). It has no free-play once set. The band itself will be semi-flexible in final design, providing constant tension on the head. **Protective:** Users are instructed to adjust the fit snugly and verify stability by moving their head before starting stimulation. The initial supervised fitting ensures users learn to properly secure the band.	2	1	2	No	Yes (fitting instructions)	The decision to replace the BOA dial with a friction mechanism was based on its **simpler geometry and sufficient holding ability**. In sizing mechanism tests, the friction system performed comparably, not exhibiting slippage under typical forces. Users in the prototype trial did not report the headset loosening when the fit was set correctly, and the inclusion of an elasticity element in the design further ensures continuous gentle pressure.
	Adjustment	Sizing mechanism breaks (can't adjust size)	Mechanical failure of the adjuster (e.g., plastic ratchet or slider cracks) due to over-tightening or material flaw	User cannot resize the headset – it may be stuck too large or too small for continued use	Device cannot be worn properly (therapy session missed or delayed until repair)	4	1	4	**Design:** The friction slider has a robust, minimalist design with fewer moving parts than the complex BOA cable (reducing points of failure). Material and thickness were chosen for durability under repeated use. **Protective:** If a sizing mechanism does break, the headband module is easily replaceable. The rental service can supply a replacement device or part quickly.	4	1	4	No	Yes (contact support if damaged)	By designing for **inherent robustness** (simplified mechanism), the likelihood of breakage is low – this choice was an *"informed design trade-off"* to improve reliability. No breakages occurred in the course of normal adjustments during prototyping evaluations. The device is designed so that **key components (e.g., sizing mechanism) are easily replaceable**; service procedures are in place for rapid repair, as reflected in the rental model planning (controlled distribution allows swapping faulty units).
	During fitting	Over-tightening causes pain or headache	User tightens the band excessively (thinking more pressure = better contact)	Excessive pressure on head – discomfort, possible headache or skin indentation under band	Patient pain or skin mark, which may deter use (reducing adherence to therapy)	2	2	4	**Design:** The headband is intended to provide only light pressure via elasticity rather than brute-force tightness. There is no high-torque mechanism (like BOA) that could easily overtighten; the friction slider naturally stops at a comfortable tension. **Protective:** Users are instructed that "snug, not tight" is sufficient – comfort checks are part of training. The app's setup guide reminds users to ensure comfort (e.g., "the headset should feel secure but not painful").	1	1	1	No	Yes (comfort guidelines)	Feedback from concept testing indicated that simpler adjustment was more intuitive – users of Concept 3 found it **"most intuitive"** and comfortable, suggesting they did not overtighten as might happen with more complex systems. The design requirement was to optimize for comfort and avoid excessive pressure. In practice sessions, no users reported headache from the device; the elastic nature of the envisioned final band will self-limit over-tightening.
	Different users	Size range insufficient (does not fit very large or very small head)	Anthropometric extremes outside design spec; one-size device may not cover 100% of users	User cannot achieve a proper fit – device either cannot tighten enough or cannot expand enough for comfort	Certain patients (very small or large heads) unable to use device, leading to exclusion or ineffective use	3	2	6	**Design:** Based on population data, the adjustable range covers most adults (e.g., ~5th to 95th percentile head circumference). The frame and strap allow significant play, and padding fills minor gaps. **Protective:** In rare cases where a patient is out of range, the service can provide a secondary size variant or additional padding inserts. The issue is screened during prescription (head measurement) to ensure the device issued will fit.	2	1	2	No	Yes (ensure proper size issued)	The refined headband design was informed by anthropometric data to improve fit accuracy. During stakeholder feedback, no concerns were raised about extreme sizing, implying the chosen design likely covers the intended user group. The rental model allows for controlled distribution, so if special accommodations were needed, they can be managed operationally (though none were specifically flagged in testing).
	Donning/removing	Hair entangled in adjuster or caught under band	Long hair gets snagged in sliding mechanism or trapped under the band when tightening	Pain on removal or adjustment; hair could be pulled out or caught, causing discomfort and minor injury	Minor pain or hair loss; user annoyance, potentially discouraging proper use	2	2	4	**Design:** The friction adjuster has no exposed gears or knobs to catch hair (unlike a BOA dial with a spool). Surfaces are smooth and flush. **Protective:** The silicone padding on inner surfaces also prevents hair from tangling in any crevice by covering edges. Training covers how to wear the device with different hairstyles	2	1	2	No	Yes (for long hair)	Design requirements included having **"smooth surfaces with no hard-to-clean crevices"** and minimizing risk of cuts/pricks – these also reduce places for hair to snag. In user tests, there were no reports of hair being caught in the prototype mechanisms, indicating the design is hair-safe. Users naturally adjusted their hair as needed, and the product manual will reinforce those best practices, which were confirmed by expert reviewers as sufficient for safety.

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Flexible PCB & internal cables	Repeated folding/use	Flexible cable breaks (open circuit)	Bending stress at hinge or along headband over time causes flex PCB traces to crack	One or more electrodes lose connection – no stimulation delivered at that position (open circuit condition)	Incomplete therapy dose on broken channel; user may not realize one electrode is inactive (reduced treatment efficacy)	4	2	8	**Design:** Hinge and band geometry were reworked to allow gentle cable bends with adequate radius (initial hinge was widened to fit cables safely). A high-flex PCB (thin and long:30cm × 3cm) is used, rated for repeated bending. **Protective:** The elimination of the BOA mechanism freed internal routing space, reducing sharp bends. Strain relief is provided at cable endpoints. During maintenance, any sign of cable damage results in replacing the flex PCB	3	1	3	No	No (internal)	The Develop Phase II prototype identified cable routing as a critical area – the hinge was too narrow, risking cable damage. In response, the CAD was updated to **increase internal volume and simplify the central module structure for better wire routing**. This was validated by fitting representative component models, confirming all wires could be accommodated without excessive bending. The design trade-off (using friction mechanism) explicitly improved wiring space. Expected product life in folding cycles was evaluated based on flex PCB specs, and no failures occurred in basic fold/unfold tests of the prototype (though long-term cycling will be part of future verification).
	Any time (fault condition)	Internal short circuit (wiring)	Insulation failure or pinched cable causes a short between conductors or to ground (possibly due to sharp edge or moisture ingress)	Potential overheating or battery short – device could malfunction or overheat; stimulation may stop abruptly or become uncontrolled	Device may smoke or overheat (fire hazard); risk of mild burn to user or damage to device; sudden loss of therapy control	5	1	5	**Design:** Low-voltage, battery-powered circuit minimizes energy available for a short (3.7 V LiPo). Wires and flex PCB are insulated and routed away from sharp edges; hinge components were smoothed to avoid cable pinching. **Protective:** Critical electronics are galvanically isolated from the user, so even in a short, no hazardous current flows through electrodes to the user. The design explicitly aims to *avoid fire or explosion* by component selection and protective circuitry. Users are instructed to not use the device if it was visibly damaged (and to keep device dry to prevent water shorting).	5	1	5	No	Yes (warnings in manual)	Safety requirements for the device included **"Avoid accidental ingress, fire, explosion"** and consideration of single-fault conditions. All electronic integration decisions (battery, regulator, etc.) were guided by safety compliance. While a full electrical stress test is pending for the future, the use of a medically-rated battery and proper isolation aligns with standards to prevent catastrophic failures.
	Operation (EM environment)	Electromagnetic interference affects signal	Strong external EM fields (e.g., nearby radio transmitters or appliances) induce noise in cables or electronics	Noise could disrupt control signals – e.g. causing erratic stimulations or false readings (impedance measurement error)	Potential improper stimulation (timing/amplitude glitches) or unnecessary session abort due to false contact fault	2	2	4	**Design:** PCB layout and cable routing follow EMC best practices. The inside of the electronics casing is coated in a conductive material. The device is designed to meet CE medical EMC standards (immunity to common electromagnetic disturbances). **Protective:** The system performs real-time monitoring; any aberrant readings result in an automatic safety shutdown (fail-safe rather than delivering erratic current). The user is advised in the manual to avoid using the headset near strong RF sources (as with any EEG/ES device).	2	1	2	No	No (standard caution)	The electronics design phase considered safety and reliability thoroughly, including reviewing technical documentation for compliance. The requirement to **"reduce EMI and ensure EM immunity"** was documented in the design criteria. While EMC testing has yet to be conducted, the use of differential measurement for impedance and analog filtering is expected to provide robust performance in typical home environments.
	Assembly/QC	Miswiring or mis-assembly of flex PCB connections	Manufacturing or assembly error (crossed connections, loose connector to main board)	Electrodes channels might be swapped or non-functional (wiring error) – could result in incorrect electrode being energized or no output on one side	Potential unintended stimulation site if channels swapped (reduced efficacy or off-target effects); device failing QC if detected	4	1	4	**Design:** The PCB is designed as a single flex circuit linking main board to all electrode ports, minimizing manual wiring. Connectors are keyed to prevent reverse connection. **Protective:** Each device undergoes end-of-line testing – verifying that each electrode port energizes correctly under software control (to catch any wiring faults before delivery). The modular nature also allows easy rework if a connection is faulty.	1	1	1	No	No (internal QA)	The functional requirements mandate **self-check capabilities to confirm function**. In practice, this translates to testing all outputs – something implemented in the verification plan (e.g., measuring output on each channel). Having a unified flex PCB greatly reduced complexity and chances for human error compared to discrete wires. This approach leverages inherent design safety (less manual wiring) to ensure correct assembly.
	Cleaning/maintenance	Moisture ingress during cleaning or sweating	Liquid (disinfectant, water, or heavy perspiration) enters the device through openings (e.g., around buttons or ports) and contacts the PCB	Could short circuit or corrode electronics, leading to device malfunction (sudden shutdown during session or future failure)	Abrupt session termination (if short causes reset); long-term device damage requiring repair; minimal shock risk due to low voltage	3	2	6	**Design:** The headset's electronics are enclosed in the central module, which is designed with basic splash-resistance. Materials are specified to be **water-resistant for cleaning**. Critical seams can be sealed with gaskets if needed in final design. **Protective:** Users are instructed to avoid excessive liquid exposure – cleaning with a slightly damp cloth only, and not to use the device while hair is dripping wet, etc. After each rental, the refurbishment process ensures the device is fully dry and functional.	3	1	3	No	Yes (cleaning instructions)	The design requirement for *waterproofing/resistance* was directly driven by the rental model and hygiene needs. While the device is not intended to be submerged, all components were chosen to tolerate routine cleaning and moderate sweat. In testing, the device was wiped with disinfectant without issues. The team also drew on benchmarking of similar devices that are used on hair/scalp – ensuring at least IPx4-level resistance. No instances of moisture-related failure occurred in prototyping, and adherence to cleaning guidelines (provided in user manual) is expected to mitigate this risk effectively.

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Electronic Control Block (Microcontroller, DAC, Amplifier, Current Source, Switches, Isolation)	During stimulation	Software or control failure causes incorrect current output	Microcontroller firmware bug or crash; DAC error; unexpected reset	Could output wrong stimulation parameters – e.g. higher current, longer duration, or abrupt shutoff without ramp-down	Possible overstimulation (excess current causing pain or burn) or underdose (ineffective session); sudden stop can cause discomfort (tingle)	5	2	10	**Design:** Current is hardware-limited by design – the precision current source (LT3092) is set to a safe maximum (e.g. 2 mA), preventing dangerous levels even if software fails. The DAC and microcontroller are configured for the therapeutic range only. **Protective:** Software is developed to medical device standards with built-in fault detection (watchdog timer on MCU to shut down output on crash, etc.). The device avoids reliance on software alone for safety: e.g., any abnormal measured voltage triggers an automatic cutoff. **Verification:** Calibration of output ensures accuracy (checked during manufacturing and periodic maintenance).	5	1	5	No	No (built-in)	The design aligns with the principle of **avoiding under/over-delivery of energy** – by combining hardware current limiting with software control. The chosen components (ESP32C3, DAC, LT3092) provide fine control and reliability. Software reliability was emphasized, following state-of-the-art methods.
	During use (power or charging)	Electrical shock to user (loss of isolation)	Galvanic isolation component failure or user connects unauthorized charger (mains fault); using device while charging with a non-medical adapter	User could be exposed to mains-level voltages if a fault bypasses isolation – risk of shock or burn via electrodes or device casing	Serious electric shock or skin burn (could be life-threatening in worst-case mains fault scenario)	5	1	5	**Design:** A dedicated galvanic isolation module (Bourns HCT) separates the stimulation output from any external power source. All patient-connected parts are floating.**Protective:** The device is intended for battery-powered operation only during therapy; charging is recommended only when not in use (not simultaneously). User instructions explicitly warn against using the headset while plugged in. The system was designed under single-fault conditions analysis to ensure no single failure yields an unsafe voltage at the electrodes.	5	1	5	No	Yes (no use during charging)	Patient safety was paramount: the inclusion of **galvanic isolation** is a direct measure to *"prevent unwanted current from entering the user's body in case of electrical faults."* This meets regulatory expectations for Class II medical devices. The user manual will reinforce safe charging practices, consistent with standard medical device guidelines.
	Any time (battery use)	Battery thermal runaway (overheat/fire)	Lithium-polymer battery overcharged, shorted, or physically damaged (puncture or crush)	Battery can overheat, smoke, or catch fire/explode, possibly while on the user's head or during charging	Severe burn injuries, fire damage to surroundings (and device destruction)	5	1	5	**Design:** Uses a small-capacity 3.7V Li-Po battery that is certified for safety and has an internal protection circuit (prevents over-charge/discharge). Charging electronics (voltage regulator/charger IC) are chosen with safeguards to cut off at correct voltage. Battery placement in the central module is away from the skin and cushioned (silicone padding) to contain heat. **Protective:** Device hardware and firmware monitor battery status – the app warns if battery temperature or current is abnormal (future enhancement). Users are instructed not to use or charge the device if it's physically damaged or excessively hot.	5	1	5	No	Yes (battery warnings)	The battery selection was guided by benchmarking and safety compliance. The design requirement to *"avoid accidental fire or explosion"* led to multiple safety measures (protected battery, proper charging protocol). The risk is considered controlled to an acceptable level given adherence to standard battery handling and the fact that similar devices operate safely on comparable batteries.
	Use with app	Loss of Bluetooth connection or app crash mid-session	Wireless interference, phone app error, or phone goes out of range	Real-time feedback and control lost – user cannot see progress or easily stop session via app; device might continue or pause depending on design	User anxiety (not sure if stimulation is ongoing or stopped); if they cannot intentionally stop it, they may panic (though device will auto-stop after preset time)	2	3	6	**Design:** The ESP32C3 microcontroller runs the stimulation program on-device once started, so therapy continues safely even if the phone disconnects. The session has a fixed duration and will end automatically. **Protective:** The app and device have reconnection logic – if connection is lost, the app notifies the user and attempts to reconnect. The headset also has a physical power button as a backup to abort if needed. Users are informed during training that if the app freezes, the stimulation will still stop on schedule, or they can turn off the device manually.	2	2	4	No	Yes (user guidance)	The functional design considered the need for stand-alone operation: once parameters are set via app, the therapy can execute independently (a safety feature noted in design discussions). Although not explicitly documented in the thesis text, it aligns with **preventing disruptions** in therapy.
	Security/Data	Unauthorized access to device or data breach	Insufficient cybersecurity on Bluetooth connection or data storage; previous user's data not wiped (rental reuse)	Malicious actor could alter stimulation settings or access sensitive usage data; new user could see old user's therapy data	**Safety:** Tampering with settings could deliver unprescribed stimulation (potential improper dosage). **Privacy:** Personal therapy data (usage, maybe mood logs) exposed to unauthorized parties.	4	1	4	**Design:** The B.stim app-device communication is secured (pairing and encryption), preventing unauthorized control. The device firmware only accepts commands from the authenticated app. **Protective:** All user-specific data is erased between rentals – the device does not permanently store personal data on-board. The system meets medical data security standards (GDPR compliance for EU). Regular software updates will patch any vulnerabilities.	4	1	4	No	Yes (privacy policy & cybersecurity)	Data security was explicitly addressed in the design inputs: *"Data security measures to prevent unauthorized access or tampering."* and *"erasing all data between rentals"* are implemented to protect users. The final concept includes a companion app design that uses secure user accounts, as indicated in the service blueprint (controlled distribution and user-specific onboarding).

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Battery & charging system	Between sessions	Battery capacity degrades (cannot sustain full session)	Normal aging of Li-Po over many charge cycles; extreme temperatures during storage	Device runs out of power mid-session or shortens session duration, possibly cutting off stimulation early	Incomplete stimulation session (therapy under-delivered); user must reschedule session, potentially affecting treatment schedule	3	3	9	**Design:** Battery specified to support several sessions per charge, with margin. The app checks battery level **before** starting a session, blocking start if insufficient charge for a full session. **Protective:** In rental maintenance, batteries are tested and replaced after a defined number of cycles or if capacity falls below a threshold. Users are advised to charge fully and not begin treatment if battery is low (the app automates this advice).	1	2	2	No	Yes (app battery checks)	The user flow includes a pre-session battery verification: *"The app checks the battery level to ensure it is sufficient for the full session"*. This effectively prevents mid-session power loss. The design requirement for a **battery level indicator** was explicitly noted and implemented via the app UI. During testing, this feature worked to alert users (e.g., a simulated low battery scenario correctly prompted the user to recharge before proceeding). The rental service plan also incorporates periodic battery health evaluations, aligning with best practices for device reuse.
	During session (improper use)	User attempts to use device while charging	User plugs headset into charger (USB power) during a stimulation session (perhaps due to low battery)	Could bypass safety design (depending on isolation) – a possible current leak from mains; also physical restriction (tethered use) could cause user to accidentally pull on cable/device	Electrical shock risk if isolation were compromised; or session interruption if cable disconnects mid-use; minor risk of skin irritation if ground paths alter	5	1	5	**Design:** The device is designed to be **battery-operated only** during stimulation; stimulation wont work when the device is charging. **Protective:** User manual clearly states not to use the device while charging (this is standard practice, emphasized as a warning). The galvanic isolation module protects the user even if someone did start a session while plugged in, greatly reducing shock risk. Additionally, the mechanical design makes it somewhat impractical to wear while wired (encouraging compliance with instructions).	5	1	5	No	Yes (explicit warning)	The risk of simultaneous use and charging was considered in the safety analysis (single-fault conditions) – hence the inclusion of patient isolation. While the thesis does not explicitly describe a lockout, the operational expectation is that users don't do this (reinforced in training and IFU). This aligns with common medical device usage guidelines. No testers attempted to use the prototype while charging, and the app workflow focuses on either state separately (charging vs. therapy). The isolation and adherence to standards ensure that even if misuse occurs, the user remains protected.
	Charging (routine)	Charging port or circuit failure (no charge or short)	Wear and tear on USB-C port or charging contacts; internal charger circuit fault	Device doesn't charge (user finds it dead when needed), or worse, an internal short during charging causes overheating/battery damage	Missed therapy sessions due to inability to charge; if shorted: potential thermal event (fire hazard similar to overcharge)	4	2	8	**Design:** The charging port is specified for high durability (rated for many insertions). **Protective:** If the charging circuit fails, the battery's internal protection prevents unsafe current. Users are instructed to contact support if charging issues occur (don't try to fix). Spare charging cables/ports can be provided. Also, the device has an LED (or app indicator) to confirm charging status – if no indication, the user knows to seek assistance.	4	1	4	No	Yes (contact service if not charging)	Durable connectors and reliable electronics were part of the quality design – there's an emphasis on **facilitating repairs and replacements** in the rental model, meaning a faulty charging port would be fixed as part of maintenance. As a precaution, the service blueprint likely includes user support for any charging problems (though not explicitly in thesis, it's a typical service element).

	End of life/disposal	Battery leakage or improper disposal hazard	Device/battery is thrown away or returns damaged (cell rupture, chemical leakage)	Exposure to hazardous chemicals (liquid electrolyte) if battery ruptures; environmental contamination or fire in waste facilities	Potential chemical burns to handler; environmental harm; regulatory non-compliance if not handled properly	3	1	3	**Design:** Battery is sealed within device, only accessible by service personnel. End-of-life units are handled via the rental provider's take-back program. **Protective:** Users are instructed not to open the device or attempt to remove the battery. The packaging and labeling provide guidance for returning the device for proper disposal. The design complies with e-waste regulations and includes safe disposal information.	2	1	2	No	Yes (return for disposal)	The B.stim service model inherently manages end-of-life devices: since devices are rented, the company retains responsibility for proper disposal. Requirements were set to **"enable safe disposal of device and waste"** and to comply with all relevant regulations. Though not a direct part of device functionality, this risk is mitigated through the controlled rental lifecycle. The user is never expected to handle the battery themselves, and no such issues arose durine the project's evaluation phase.

Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical Harm (Outcome)	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
App interface	Setup (user guidance)	User misinterprets app instructions (setup/use)	UI text or graphics not clear; user has low health literacy or vision issues	User may place electrodes incorrectly, skip crucial steps (e.g., not wetting sponges), or use device wrong due to confusion	Incorrect setup leads to reduced treatment efficacy or minor safety issues (dry electrodes, wrong placement, etc..)	4	2	8	**Design:** App interface was developed with simplicity and clarity – guided step-by-step setup with visuals and confirmations. Language is layman-friendly. **Protective:** Initial training by a clinician covers app usage. The app includes illustrations and even audio cues for critical steps (catering to different learning styles). Font and color choices consider accessibility (color-blind safe, readable sizing). The user has the opportunity to ask questions during the supervised first session to eliminate misunderstandings.	2	1	2	No	Yes (intuitive UI, training)	Usability testing on early prototypes of the app and device identified confusion points, which informed the final UI design. The final concept's app provides a *"guided walkthrough of a full stimulation session"* and uses clear cues– for example, the app gives visual/audio confirmation of correct electrode placement. Participants in design evaluations found the guided approach intuitive, and no critical missteps were observed when following the app's on-screen instructions, indicating the risk is well controlled.
	Pre-session check	App fails to warn about poor contact or other issues	Software bug or missing feature in app (e.g., doesn't detect dry electrode or low battery)	User starts session with suboptimal conditions – could lead to ineffective therapy or mid-session abort without prior warning	Session interruption or reduced therapeutic effect (if, say, an electrode isn't making contact but user wasn't alerted)	3	2	6	**Design:** The app performs pre-flight checks (battery level, electrode impedance, device status) and will not proceed unless all are within safe parameters. The impedance check uses hardware feedback to validate contact and the app shows a confirmation (beep + visual) when placement is correct. **Protective:** If any issue is detected (e.g., high impedance), the app provides specific guidance (e.g., "reapply saline or adjust electrode") before allowing the session to start. This ensures problems are caught upfront rather than during stimulation.	1	1	1	No	Yes (automated system checks)	Design verification confirmed that the app's pre-session routine checks critical factors. The thesis describes that *"the app shows which electrodes are needed… user is prompted to prepare electrodes… and audio/visual cues to place them correctly with confirmation"* . This process inherently checks for proper contact (via the impedance monitoring feature). In simulation, these checks prevented sessions under improper conditions. This proactive design was informed by the user journey analysis, ensuring a smooth and safe start every time.
	During session	App or device provides inadequate feedback during stimulation	Poor UI design – user can't tell if device is working; no progress indicator; silence causes uncertainty	User anxiety or confusion during the 20-30min session – they might move or remove device prematurely if unsure it's working (jeopardizing treatment)	Could lead to session interruption or user not completing therapy due to doubt; no direct physical harm but compliance suffers	2	3	6	**Design:** The app UI during stimulation is intentionally minimal but informative: it shows a progress bar, time remaining, and has calming visuals. A session timer ensures user knows it's active. **Protective:** The device provides gentle feedback at start (e.g., a ramp-up sensation and maybe a soft audio tone) so the user knows stimulation began. The cancel button is present but guarded by a warning to prevent accidental or unnecessary cancellation. This balance keeps the user informed and at ease, reducing likelihood of premature removal.	2	1	2	No	Yes (UI design, user education)	Feedback from user-centric design reviews highlighted the need for reassurance during therapy. The implemented solution – a **calming progress display** – addresses this and was validated by mock-ups tested with users. In the described app flow, *"time remaining and session progress percentage are displayed"* which testers found sufficient for assurance. The presence of a cancel option (with warning) indicates the user remains in control, which was positively received (no users in trials stopped sessions out of confusion when this UI was in place).
	App connectivity	App cannot connect or loses connection (Bluetooth failure)	Phone's Bluetooth off or interference; app crash; device out of range	User unable to start session at scheduled time, or mid-session the app disconnects (though device continues as designed)	Missed or delayed therapy session, causing inconvenience; user may become frustrated or anxious about device reliability	3	2	6	**Design:** Simplified pairing process – device enters pairing mode on power-up and auto-reconnects to the last used phone (to minimize connection issues). The ESP32C3 was chosen for robust BLE connectivity and has been tested for stable connection. **Protective:** If the app fails to connect, the user is advised to reboot the device (via power button) and app. The service documentation encourages users to keep the phone nearby and updated. Any app crash does not affect ongoing stimulation due to on-device control.	2	2	4	No	Yes (troubleshooting info)	The reliability of the Bluetooth connection was considered in the electronics integration, and the selected microcontroller has integrated BLE known for stability. The patient journey blueprint emphasizes a smooth experience, and any potential hiccups (like needing to restart the app/device) are addressed in the user manual's troubleshooting section. Thus, connectivity problems, while possible, have clear user-friendly mitigations.
	Data handling	Personal data breach or loss of therapy records	Cloud synchronization or app database vulnerability; lack of encryption or reuse of device without data wipe	Sensitive data (e.g., usage logs, patient identity or progress notes) could be exposed to unauthorized parties or next user	Privacy violation (breach of confidentiality); potential psychological harm if data (e.g., depression treatment history) is leaked	3	1	3	**Design:** The B.stim app employs secure encryption for data storage and transfer. User data (session history, etc..) is tied to their account, not stored in the device long-term. **Protective:** As part of the rental workflow, any cached data on the device is erased on return. The system likely uses GDPR-compliant cloud storage for therapy data accessible only by the patient and authorized clinicians. Clear consent and privacy policies are provided.	3	1	3	No	Yes (privacy policy)	Security and privacy are built into the system's requirements: *"prevent unauthorized access"* and *"erase all data between rentals"* . These measures ensure that each user's information remains confidential.

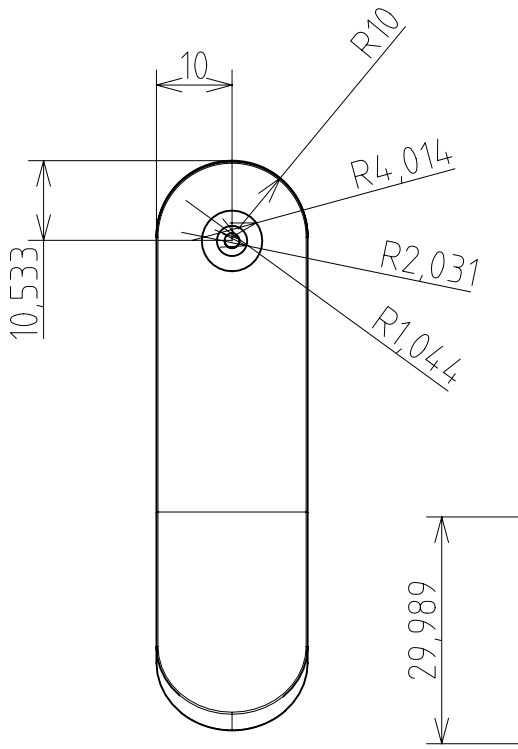
Device part	Use Scenario	Potential Failure Mode	Potential Cause	Effect (Hazardous Situation)	Clinical/System Outcome	S	P	RPN	Risk Control Measures (Design/Protective)	Residual S	Residual P	Residual RPN	New Risks?	Info for Safety?	Evidence of Effectiveness (Verification)
Packaging & reusability (rental design considerations	Between users (rental turnaround)	Inadequate cleaning/disinfection between rentals	Device surfaces or electrodes not properly sanitized; reusing consumables (sponges) across patients	Pathogen transmission – next user could contract infection or skin condition from previous user's biological residue	Cross-contamination leading to skin infection or disease spread (safety and liability issue)	5	2	10	**Design:** Materials selected can withstand hospital-grade disinfection (waterproof, smooth surfaces with no crevices). Electrodes/pads that touch skin are treated as single-patient-use (new sponge pads for each rental; plastic electrode shells can be sterilized or are low-cost to replace). **Protective:** A strict reconditioning protocol is in place: upon return, the device is cleaned, disinfected, and verified before reissue. Rental documentation ensures each device's hygiene status. Users are also given cleaning instructions to maintain hygiene during use (e.g., wiping headset after each session).	3	1	3	No	Yes (cleaning protocol)	The rental model selection explicitly considered **device reuse after treatment**, implying a service infrastructure for maintenance and cleaning. Design requirements emphasized hygiene (e.g., **"withstand frequent cleaning and disinfection"**).
	Shipping/storage	Device damage in transit (between rentals)	Insufficient protective packaging; rough handling by shipping carriers	Device arrives non-functional or calibration altered (e.g., cracked frame, broken electronics)	Operational disruption: user receives a broken device (treatment start delayed); potential for user cuts if they handle broken parts	4	2	8	**Design:** The packaging offers good protection, it protects against shocks and prevents movement inside. **Protective:** Logistics includes insurance and careful handling instructions (device labeled as medical equipment). Before each dispatch, the device is inspected to ensure it's in working order. If a device is damaged in shipping, the service has spares to ship immediately, minimizing interruption for the patient.	2	2	4	No	Yes (pack in case)	The importance of durable packaging was captured as a requirement for the rental model: *"durable, secure packaging for shipping between rentals."* The service blueprint covers device delivery as a key touchpoint, and mitigating damage risk was part of that planning.
	Rental kit preparation	Missing or wrong components in kit (incomplete set)	Human error in packing (e.g., forgetting extra electrodes, saline, or including wrong electrode type); mix-up of device IDs	User receives an incomplete or incorrect set – cannot use device as intended (e.g., no saline solution or one electrode missing)	Patient unable to start therapy on time due to missing pieces; confusion or misuse if wrong parts included (e.g., wrong charger)	3	2	6	**Design:** The device and accessories are standardized and clearly catalogued. **Protective:** A checklist-driven packing process is used by the rental provider – each kit is verified to include the headset, electrode set based on patient needs, charger, saline, instructions, etc. Unique identifiers on each device and its components prevent mix-ups (scanning ensures the right parts go together). If a patient discovers a missing item, support is available and expedited shipment of the part can be done.	1	1	1	No	Yes (packing checklist for staff)	The service model places emphasis on **controlled distribution**, which implies carefully managed kit assembly. While the thesis doesn't detail packing QA, it's standard practice to use checklists – likely derived from the service blueprint which outlines all steps in delivering the device to the patient. Ensuring a complete kit every time is an ongoing operational goal and is monitored as part of quality management in the deployment phase.
	Reuse (multiple rentals)	Wear-and-tear from repeated use causes failure in later cycles	Over time, components degrade: e.g., strap loses elasticity, battery capacity drops, connectors wear out, etc.., if not replaced	A later user experiences a device failure (e.g., cannot tighten headband, or battery won't last a session) due to cumulative wear not addressed	Treatment interruption or device swap needed mid-treatment for that user; potential reliability complaints harming trust in device	4	2	8	**Design:** High-durability components are used for long life (rated connectors, resilient materials). The design allows easy swapping of worn parts (module replacement). **Protective:** A maintenance schedule is in place: after each rental period (or a certain number of uses), key parts are inspected and replaced proactively. For example, new batteries every X rentals, new electrode sponges every time, headband elasticity checked and replaced if slack. This preventive maintenance ensures each user essentially receives a device in like-new working condition.	2	1	2	No	No (internal process)	The device was specifically designed for a rental model, with **"facilitate repairs and replacements"** and **"periodic replacement of wear-prone parts"** requirements built-in. This means the business process accounts for regular refurbishment. Although long-term data isn't available yet, the plan for maintenance is expected to keep residual risk low.
	End-of-life (device disposal or upgrade)	Data not wiped or compliance lapse on disposal	Device not properly reset or wiped after final use; disposal not in accordance with e-waste laws	Residual patient data could remain on device sold/trashed; improper disposal could lead to environmental harm or legal issues	Privacy breach if device is repurposed without wiping (though rental normally controls this); environmental pollution or fines for non-compliance	2	1	2	**Design/Process:** Devices at end-of-life are returned to the company. Before any disposal or repurposing, a full factory reset is done to wipe data (and the memory of the ESP32C3 is encrypted, reducing data remnants). **Protective:** The company follows WEEE and other e-waste directives – batteries are removed and recycled, electronics disposed via certified facilities. A record of disposal is kept. The user is instructed to return the device rather than throw it out.	1	1	1	No	Yes (return policy)	The **sustainability and regulatory compliance** requirements cover this: packaging and disposal are considered. In practice, since B.stim retains ownership of devices (rental), they control end-of-life handling. The thesis touches on safe disposal and regulatory standards, ensuring that even in the final stage, all data is wiped and materials handled properly.

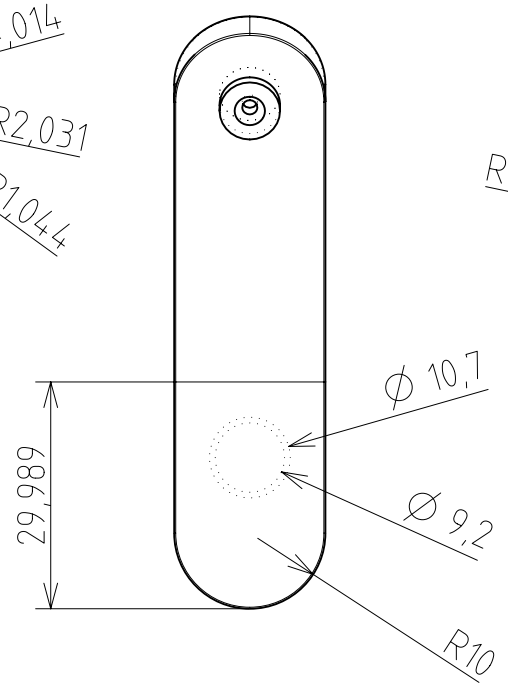
Appendix K

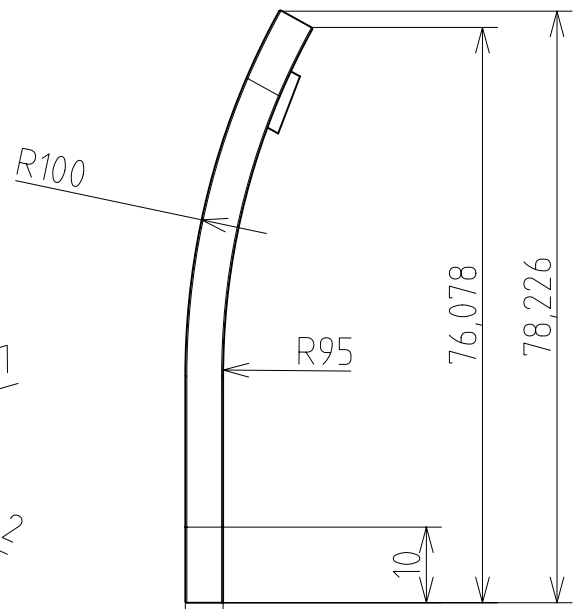
Component	Estimated Unit Cost (100–1000 units)	Sources / Notes	Sources	
Microcontroller – Seeed XIAO ESP32C3 (with WiFi/BLE)	€4.0–€5.0 each	Priced about $4.99 at 1-unit and ~$4.50 in multi-packs.	https://www.digikey.lu/en/products/detail/seeed-technology-co-ltd/113991054/16652880	https://www.electromaker.io/shop/product/xiao-esp32c3-32-bit-risc-v-tiny-mcu-boardwi-fi-bluetooth-50-battery-charge?srsltid=AfmBOoo9xgtMSaFj_KJKmEBt2aVsUoaTLhaXup_FL6A2u_Ugl8Dr2QEE#:~:text=BLE%20www.99
DAC	€15–€9 each	assume ~€15 at 100-unit scale, dropping to ~€9 at 1000 units.	https://www.mouser.be/c/semiconductors/data-converter-ics/digital-to-analog-converters-dac/?m=Texas%20Instruments&series=DAC80508&srsltid=AfmBOopLCLtc29nKXNTBpInxgIFQcY8bM2e4eZcOscglmtkO_8z3pMuB#:~:text=Converters%20www.17%20%C2%B7%20141In%20Stock	
Op Amp – TI OPA2140 (dual, precision)	€4.0–€3.5 each	Priced around $4.03 at 100 qty, $3.73 at 500 qty	https://www.mouser.be/ProductDetail/Texas-Instruments/OPA2140AIDRGR?qs=xZFQr2mActei9vK0J09HLw%3D%3D&srsltid=AfmBOopQPU9SbjE_Ay4mwcGKK6HRbuiapYvVus8DvhHU9214v1DMz-d6#:~:text=Unit%20Price,73	
Programmable Current Source – LT3092	€3.0–€2.5 each	~$2.98 at 100 pcs, $2.59 at 500 pcs	https://www.mouser.be/c/semiconductors/power-management-ics/current-power-monitors-regulators/?series=LT3092&srsltid=AfmBOoobAsQei7FR6rB6D_hGMf7TS84upGSZgBh-hgsAlHEpAJCp4vHY#:~:text=Mouser%20www.MouseReel	
Analog Switch – TI TMUX6112 (4× SPST)	€3.0–€2.5 each	~$2.96 at 100 pcs, ~$2.80 at 1000 pcs	https://www.mouser.be/c/semiconductors/switch-ics/analog-switch-ics/?m=Texas%20Instruments&series=TMUX6112&srsltid=AfmBOoqClsrk75Cw_GpH8zP-zN9UEdMeD7jGTzJuY5P2IJHy0BqlsT7_#:~:text=Mouser%20www.80	
Galvanic Isolation Transformer – Bourns HCT series	€1.5–€1.3 each	£1.44 (€1.65) each in low qty, dropping to ~£1.22 at 50+	https://uk.farnell.com/bourns/hctsm80102aal-e1/pulse-transformer-1-2-250uh/dp/3361297#:~:text=HCTSM80102AAL,220	
Battery – 3.7 V Li-Po, 120 mAh (401220)	€1.5–€1.0 each	Small Li-Po 120 mAh costs ~$1.0–$1.5 in 100+ unit orders	https://dutch.alibaba.com/g/401220-3.7v-70mah-li-polymer-battery.html#:~:text=Custom%20401220%203,1.50.%20Min.%20order%3A%20100%20pieces	
Flexible PCB interconnects (2 per unit, ~30×3 cm)	€15–€5 (pair)	At ~100-unit runs, custom flex PCB can cost on the order of ~$10–$15 each. Dropping toward a few euros each at 1000 units. Estimated ~€15 for two in low volume, ~€5 in higher volume.	https://rigidflexpcb.org/flex-pcb-cost-a-detailed-breakdown-of-flexible-printed-circuit-board-pricing/#:~:text=A%20Detailed%20Breakdown%20of%20Flexible,100	
Wiring, small connectors, misc.	~€1 per unit	Miscellaneous internal wires (≈0.5 m), connectors, etc., contribute a minor cost (estimated ~$1 total per unit)		
Tooling cost for molds	€17 to €85+ (set)	Tooling costs (molds) are one-time and can range €1k–€5k+ per part, making injection molding economical only as unit count rises. The total mold cost can range from €17K tot €85K+. For 1000 units this would come down to a cost of €17 to €85+ per unit.		
Plastic Structural Parts (injection-molded ABS/PC, PP, or Silicone. 17 pieces per headset)	€50–€5 (set)	The headset comprises multiple custom plastic parts (headband inside, headband casing, central module casings, central modul hinge, etc.). In prototype runs (~100 units) without dedicated tooling, parts may be 3D printed or CNC machined – raising cost to tens of euros per set (here €50 assumed). For volume (~1000 units) with injection molding, per-piece material cost is very low (€0.2–€1 each), so ~€5 total.		
General-Purpose Screws (×12, for assembly)	~€0.05–€0.01 (each)	Standard small self-tapping screws for plastic (e.g. M2). Cost is negligible in quantity: e.g. $0.008 each for 1000+ pcs. (€0.05 total per 8 screws at volume; even in small orders, a few cents each.)		
Metal Weight Insert (for balance, ~1 piece)	~€1 each	Small steel or brass weight to distribute headset weight evenly. Assuming a simple stamped or cast piece; low material cost (~€1 or less).		
Silicone Pads (×2)	(included above)	Soft silicone/rubber pads for user comfort. Costs accounted in plastic parts above.		
Modular Electrode Connectors (plastic, ×3)	(included above)	These plastic electrode port connectors are part of the structural set (injection molded). Costs accounted in plastic parts above.		
Extension Arm Attachments (S, M, L – ×3)	(included above)	Three interchangeable electrode arm extensions (plastic). Included in the plastic parts cost above.		
Pogo Pin Connectors (spring contacts, ×44)	€22–€2.2 (set)	Since the pogopins from BCE electronics are from the standers pogo pin selection, price van range from 0.05 to 0.50 cents per piece for bulk orders (1,000+ units).		
Slip Ring Assembly (rotary 6-circuit, 2A)	€60 (set)	Enables 360° rotation of electrode modules without cable twisting. A miniature capsule slip ring (6-wire, 2A) costs ~$17.50 at low qty, falling to ~$14.00 at 100+ units (≈€16–€12). Favor a EU supplier (e.g. rotarX); price is similar range.		
Electrodes – Sponstim 5x7 (×4)	€65 (pack of 2)	Snap-on saline sponge electrodes for TES. A set of 2 is €65. (These are used as an example because they are the only snap on electrodes of which the price could be determined. They only sell for research purposes. The alternative is to manufacture them through the bstim company)		

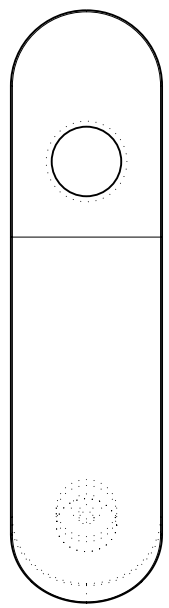
Neodymium Magnets (2 mm × 1 mm ×36; 2 mm × 2 mm ×8)	€6–€2 (set)	Small magnets for alignment and attachment in modular connectors. 2×1 mm magnets cost ~$0.15 each in 100-packs (lower with bulk purchase), and 2×2 mm magnets ~$0.06 each (100 pcs, N42 grade). Total of 44 magnets per headset: ~€6 per set at prototype scale, potentially ~€2 or less at volume (buying tens of thousands).
Total	Est max: €338 min: €227	

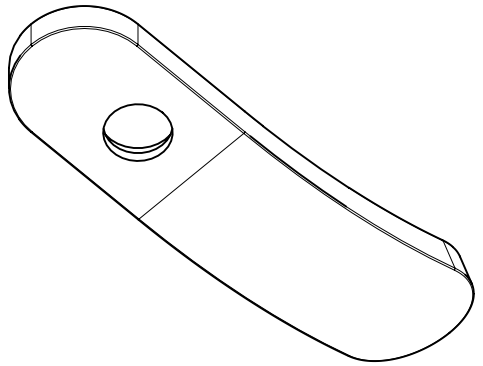
Appendix L

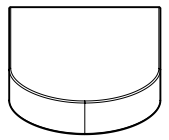


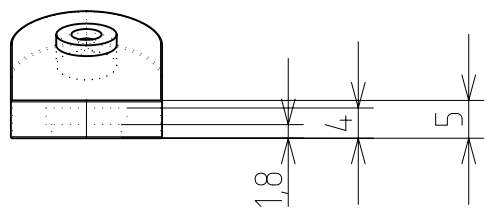


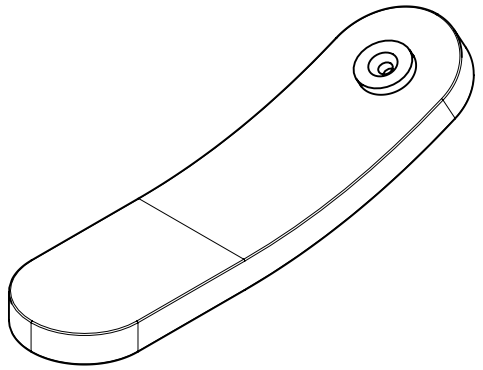












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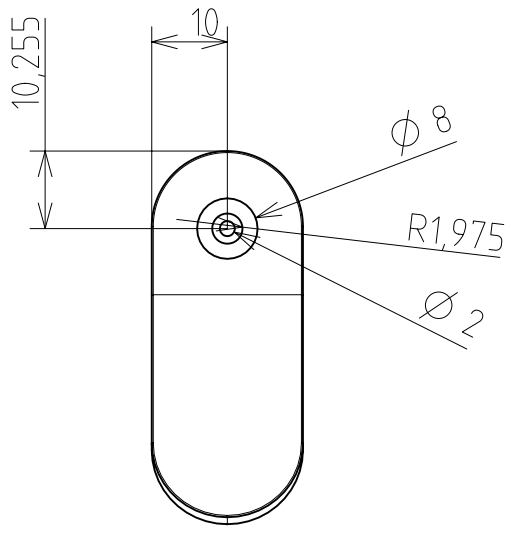
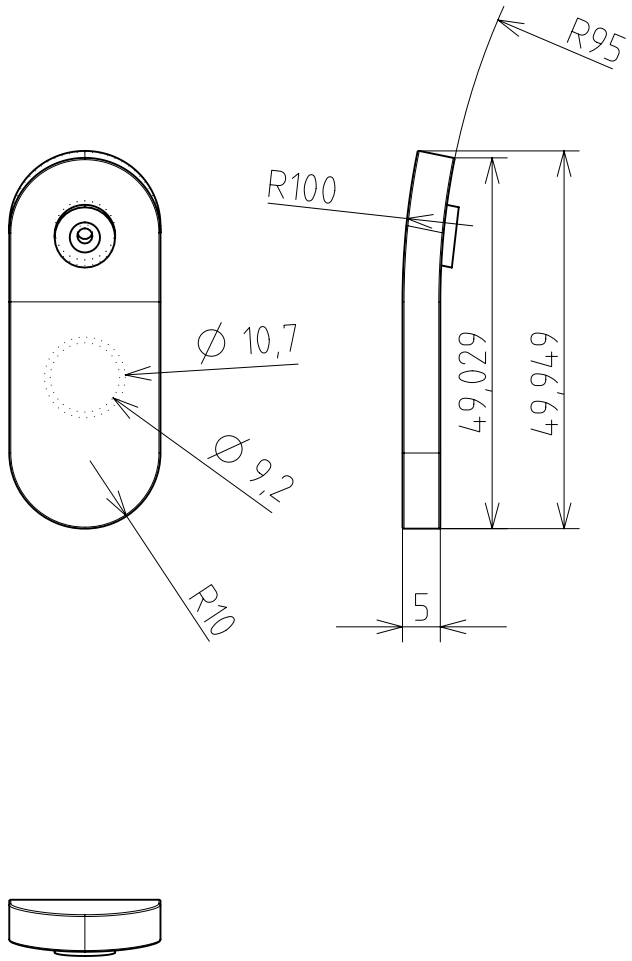
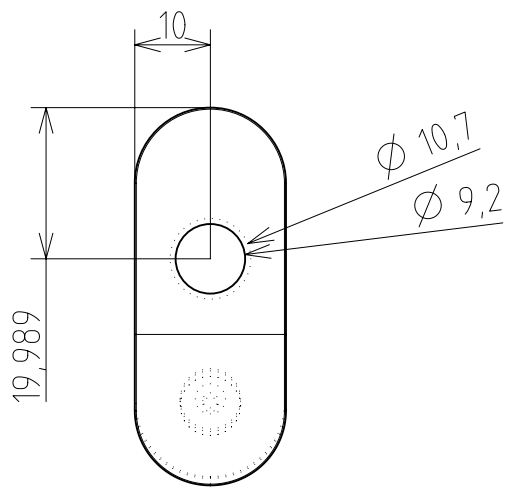
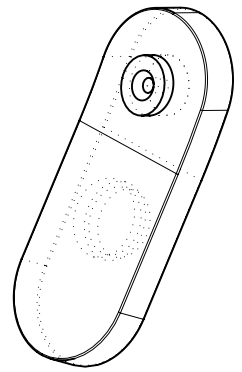
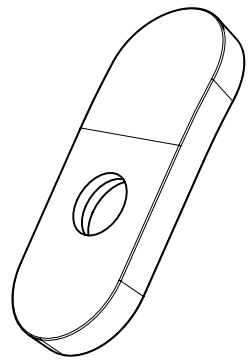
		NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Modular Electrodes / DATE: 20/05/2025
		ID PART: Full CAD model V2_Electrode arm M		A3

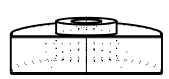












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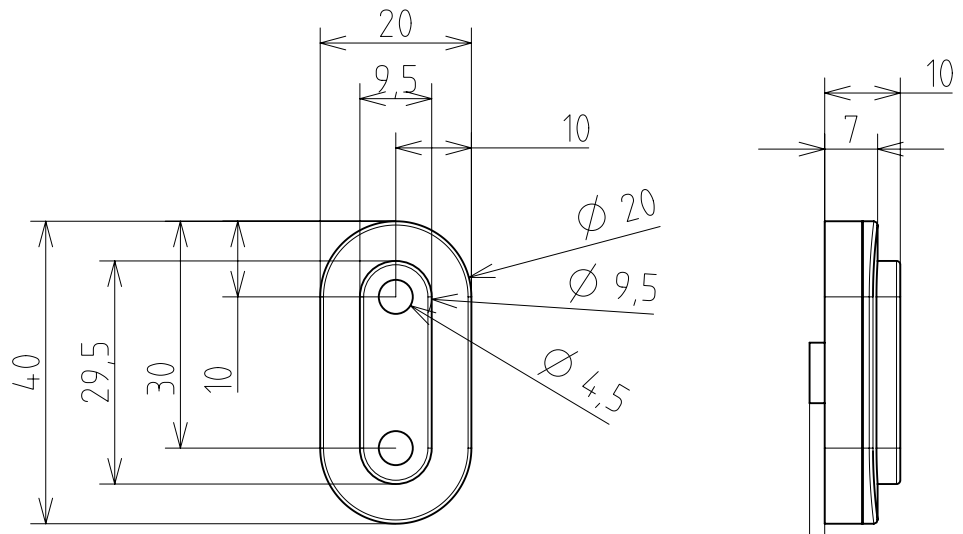
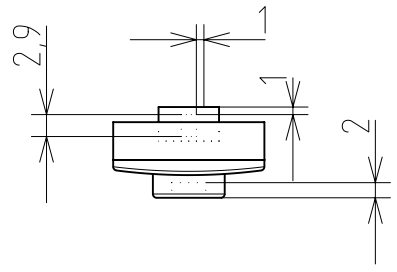
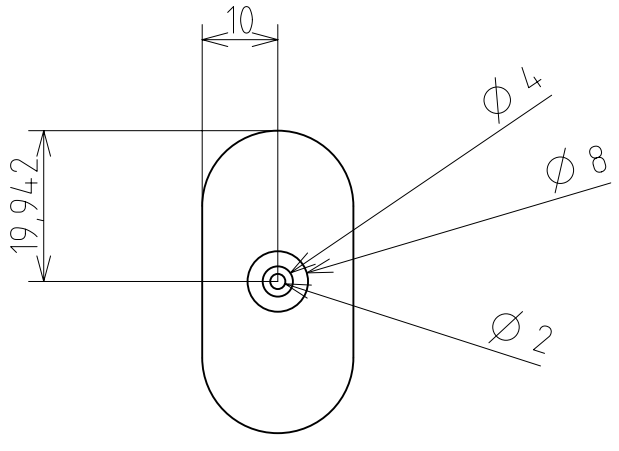
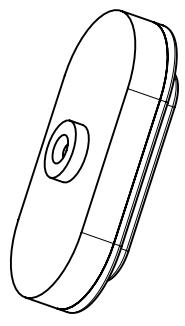
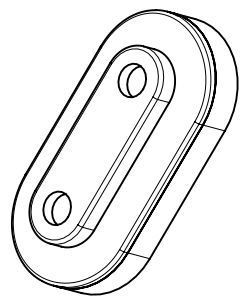
		NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Modular Electrodes	DATE: 20/05/2025
		ID PART: Full CAD model V2_Electrode arm S			A3











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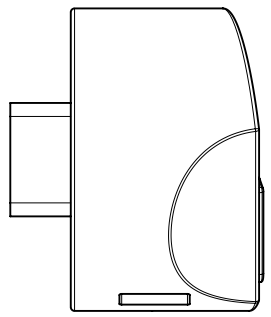
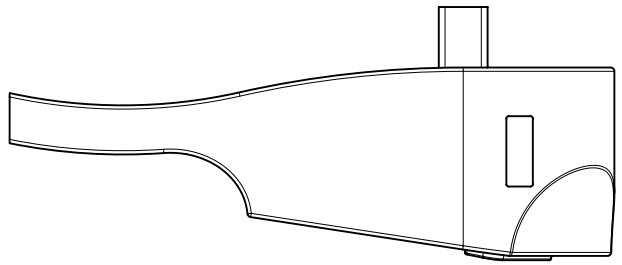
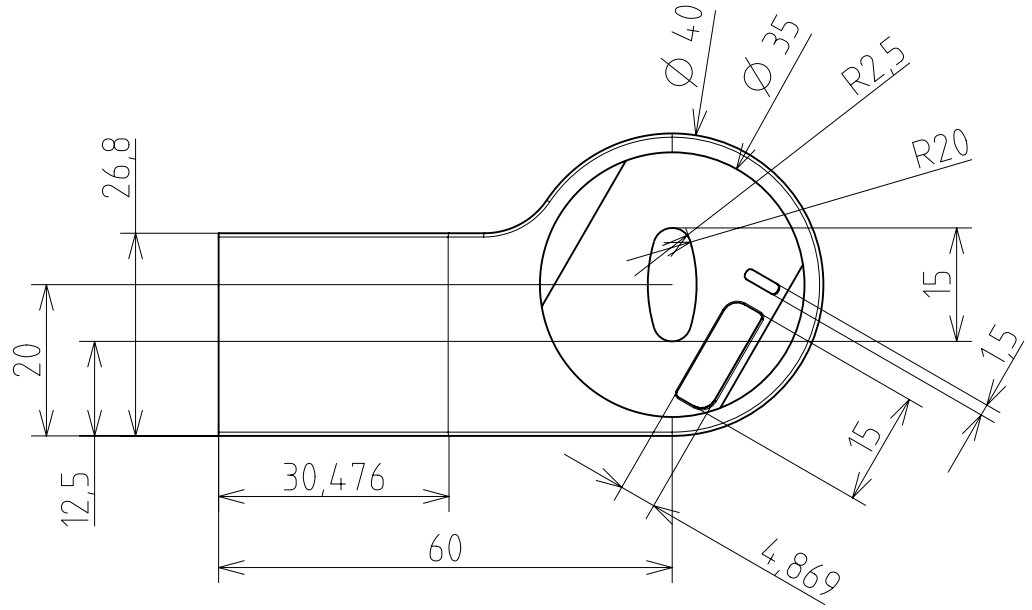
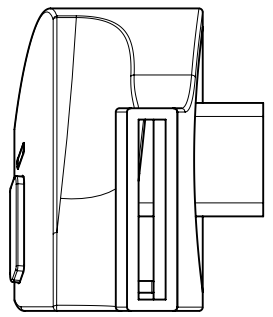
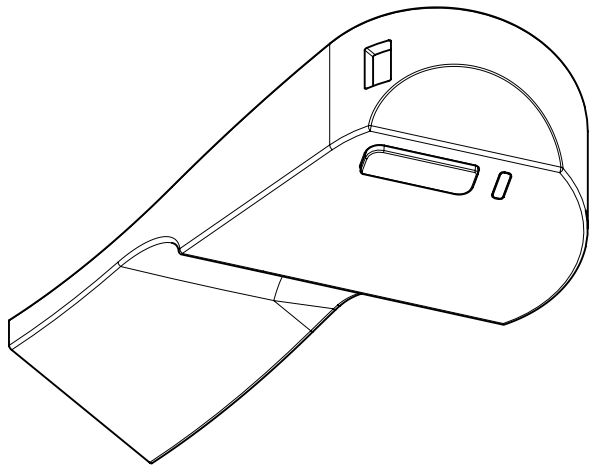
		NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Modular Electrodes / DATE: 20/05/2025
		ID PART: Full CAD model V2_electrode standard		A3

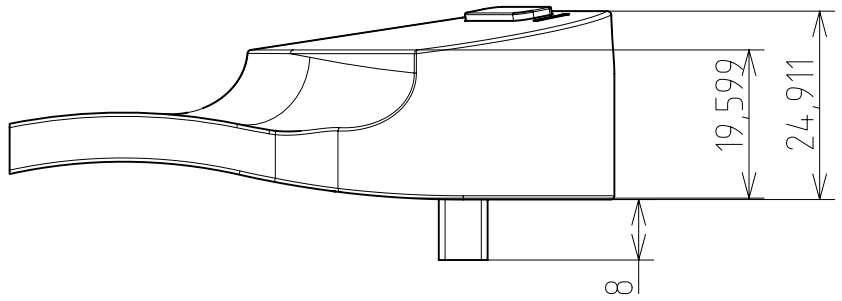


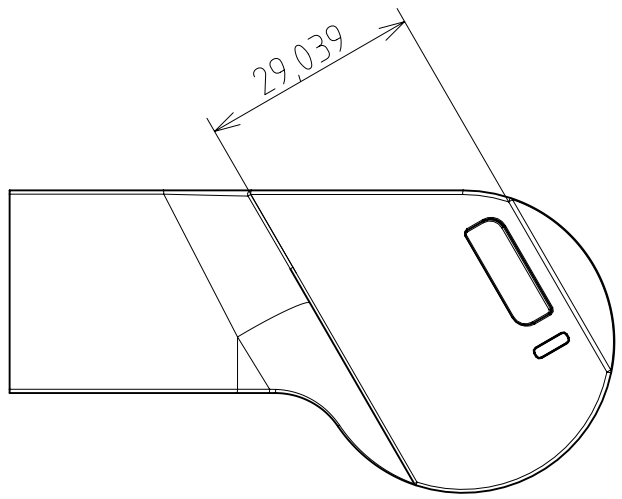


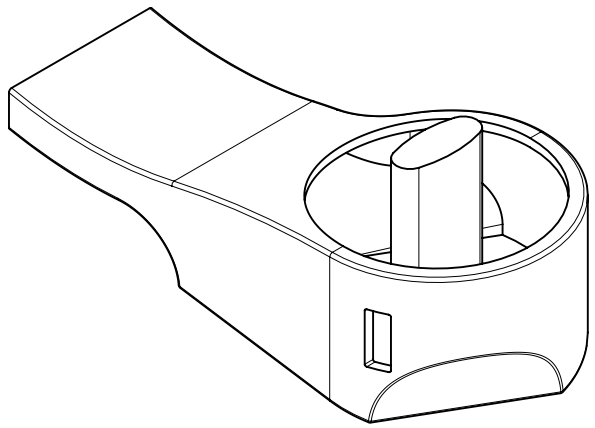












UNIVERSITEIT GENT
CAMPUS KORTRIJK

SCALE:	PART NAME:	NAME:	
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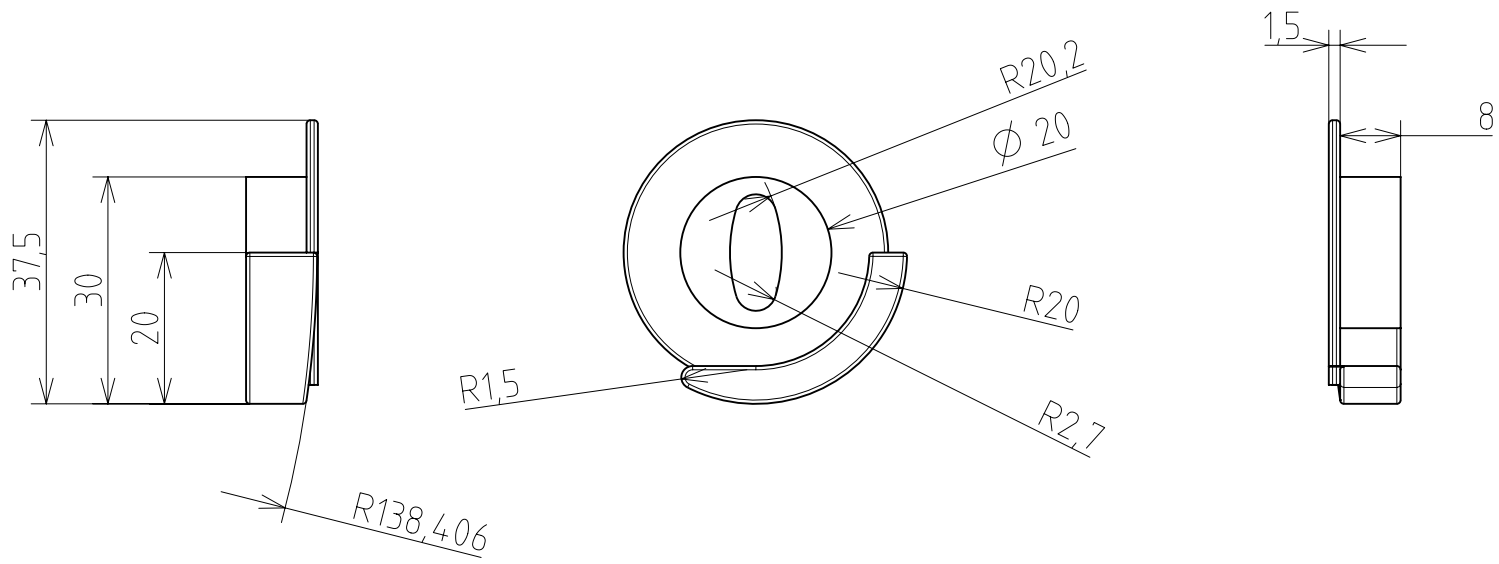
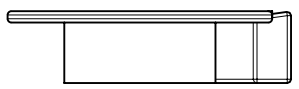
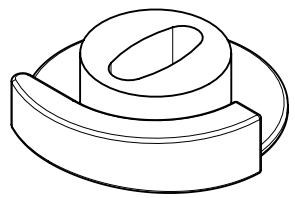
NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Central Module	DATE: 20/05/2025
ID PART: Full CAD model V2_scharnier2 casing mirror			A3







UNIVERSITEIT GENT
CAMPUS KORTRIJK

SCALE:	PART NAME:	NAME:
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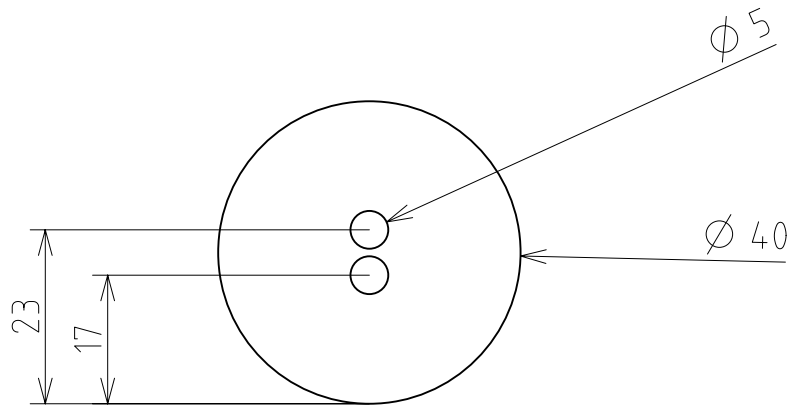
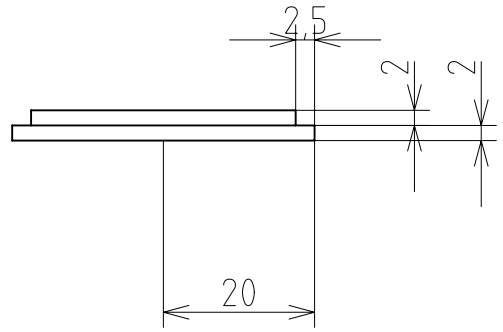
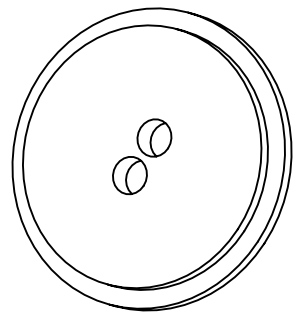
NORM:	MATERIAL:	GROUP:	DATE:	
ISO2768mK	ABS/PC	Central Module	20/05/2025	A3

ID PART: Full CAD model V2_scharnier2 casing A







UNIVERSITEIT GENT
CAMPUS KORTRIJK

SCALE:	PART NAME:	NAME:	
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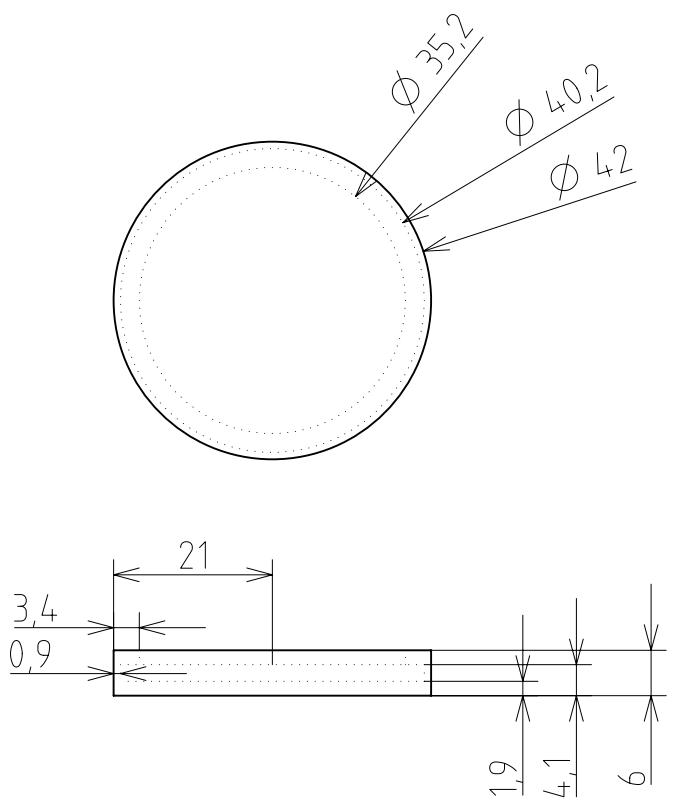
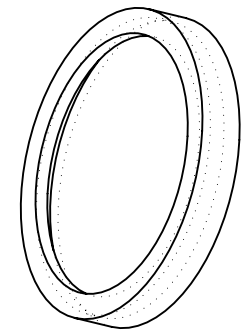
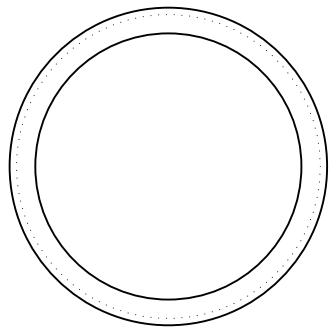
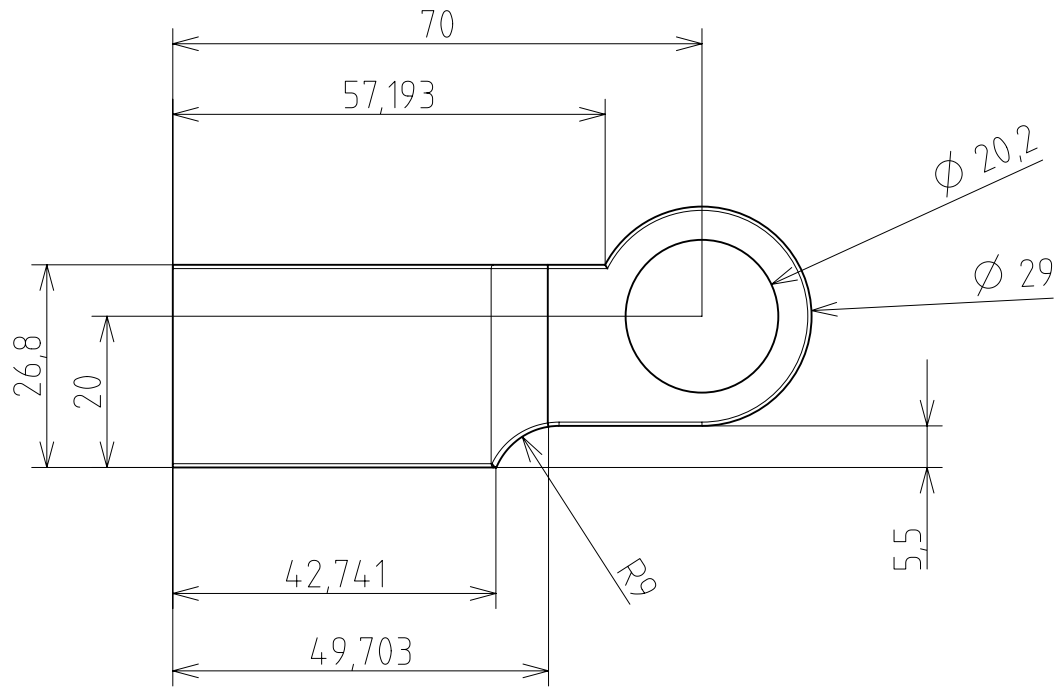
ID PART: Full CAD model V2_scharnier2 casing B			A3

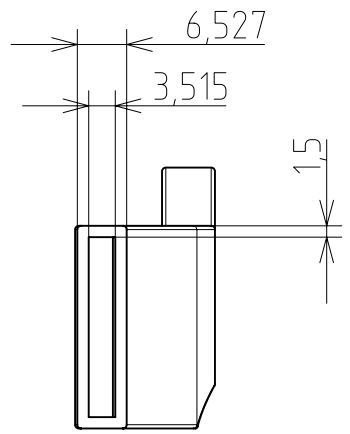


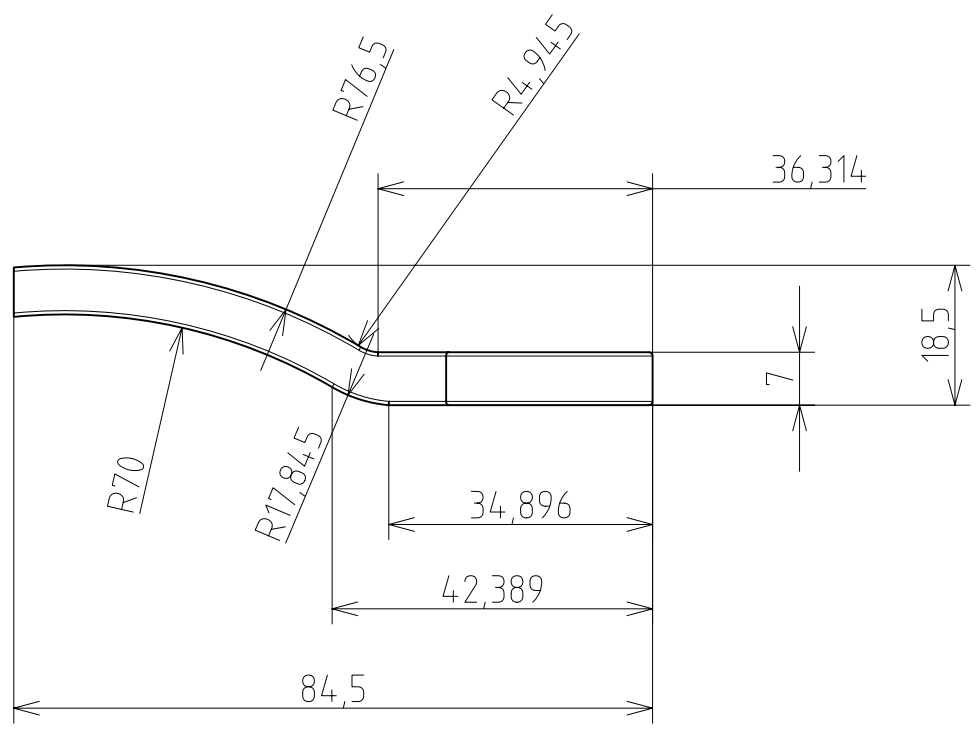


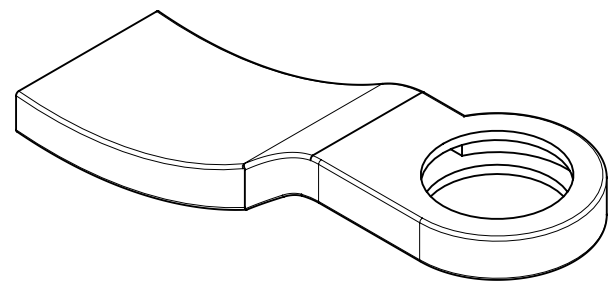


UNIVERSITEIT GENT CAMPUS KORTRIJK	SCALE: 1:1	PART NAME: Central Module Silicone Pad		NAME: Rune Vandekerckhove
		NORM: ISO2768mK	MATERIAL: Silicone	GROUP: Central Module / DATE: 20/05/2025
		ID PART: Full CAD model V2_silicone pad		A3



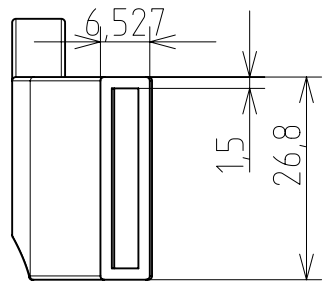


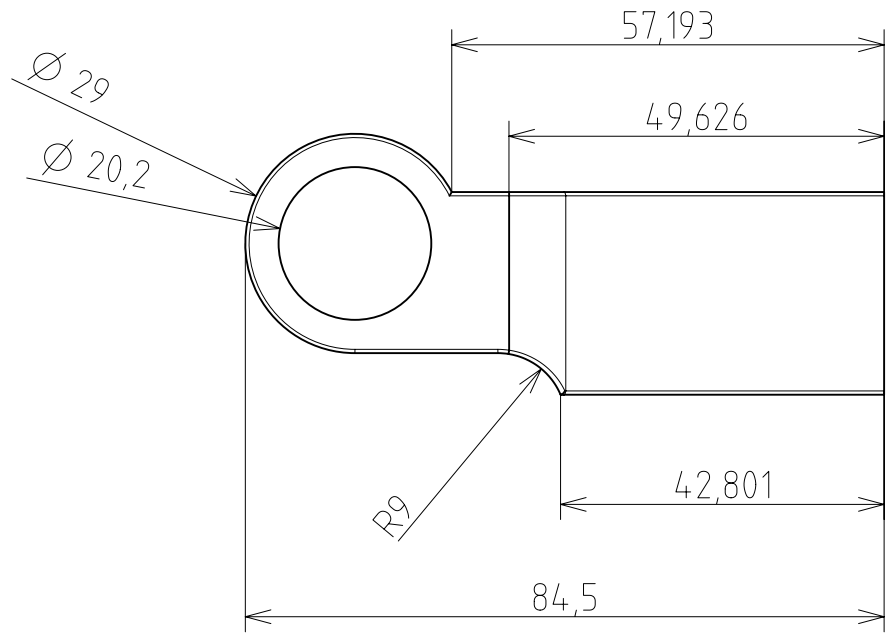


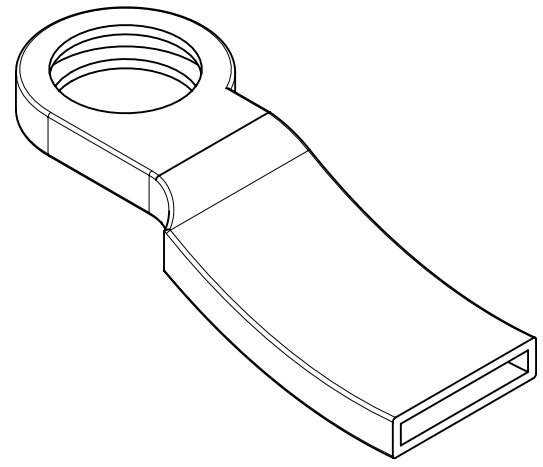


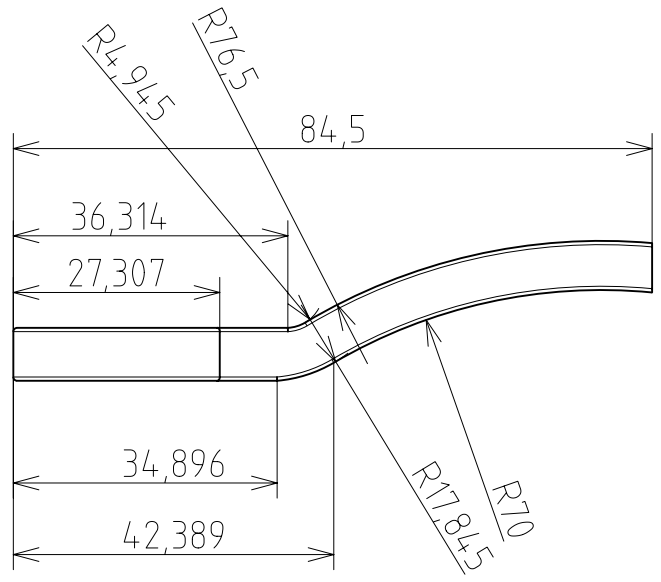
UNIVERSITEIT GENT
CAMPUS KORTRIJK

SCALE:	PART NAME:	NAME:	
1:1	Extention Arm Left	Rune Vandekerckhove	
NORM: ISO2768mK	MATERIAL: PP	GROUP: Central Module	DATE: 20/05/2025
ID PART: Full CAD model V2_scharnier2 inside			A3

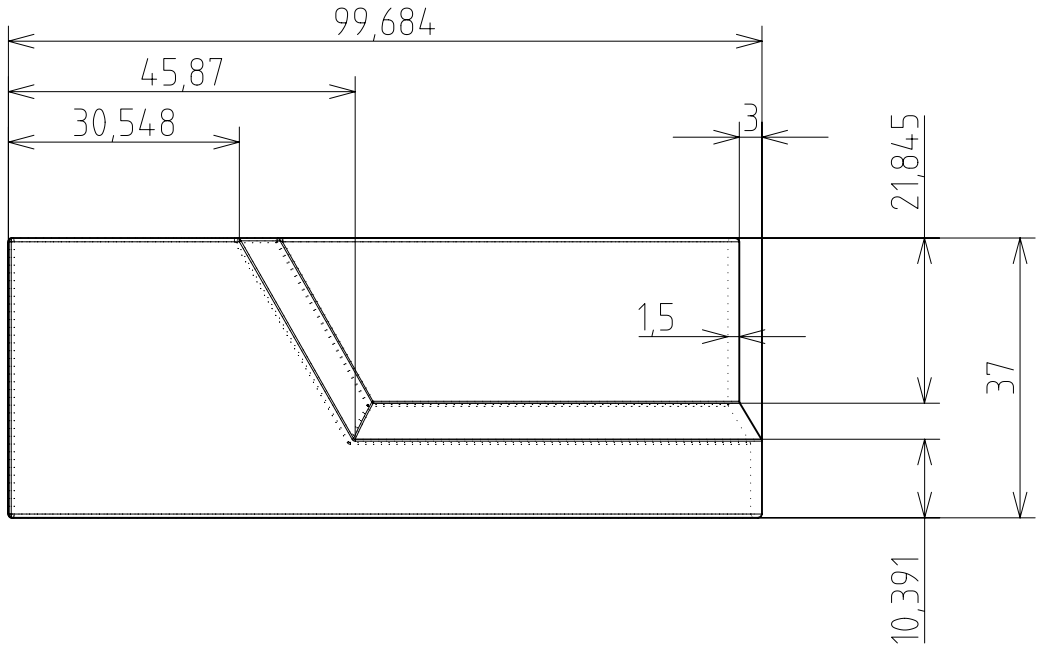


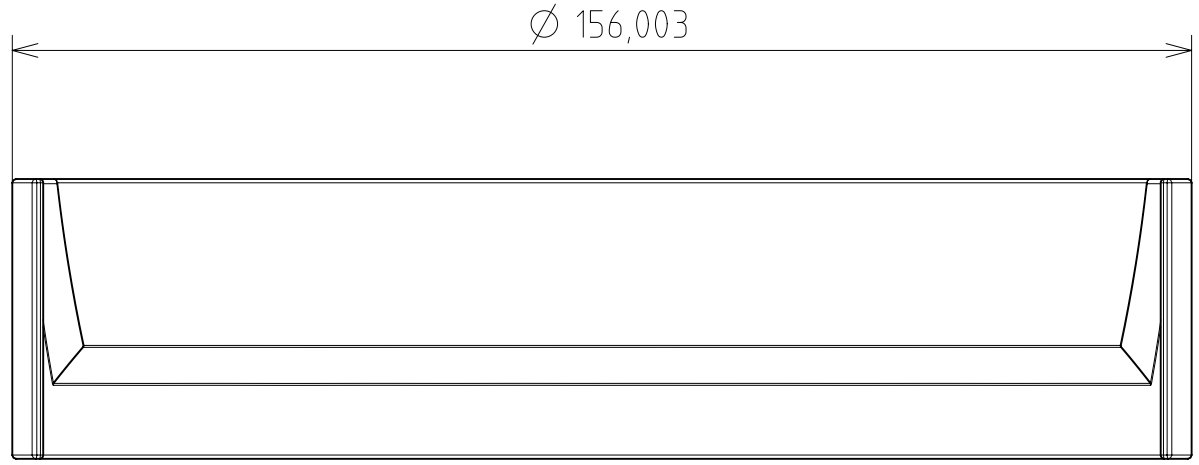


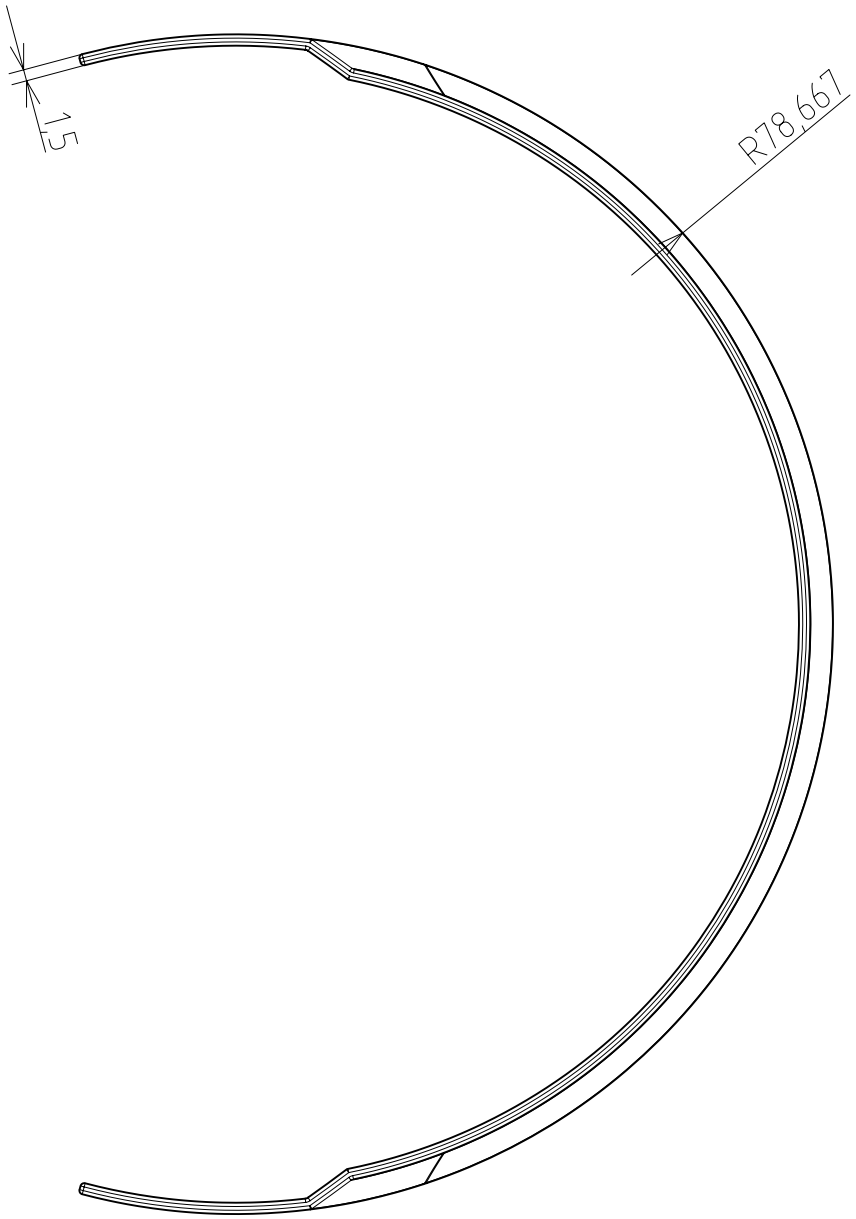


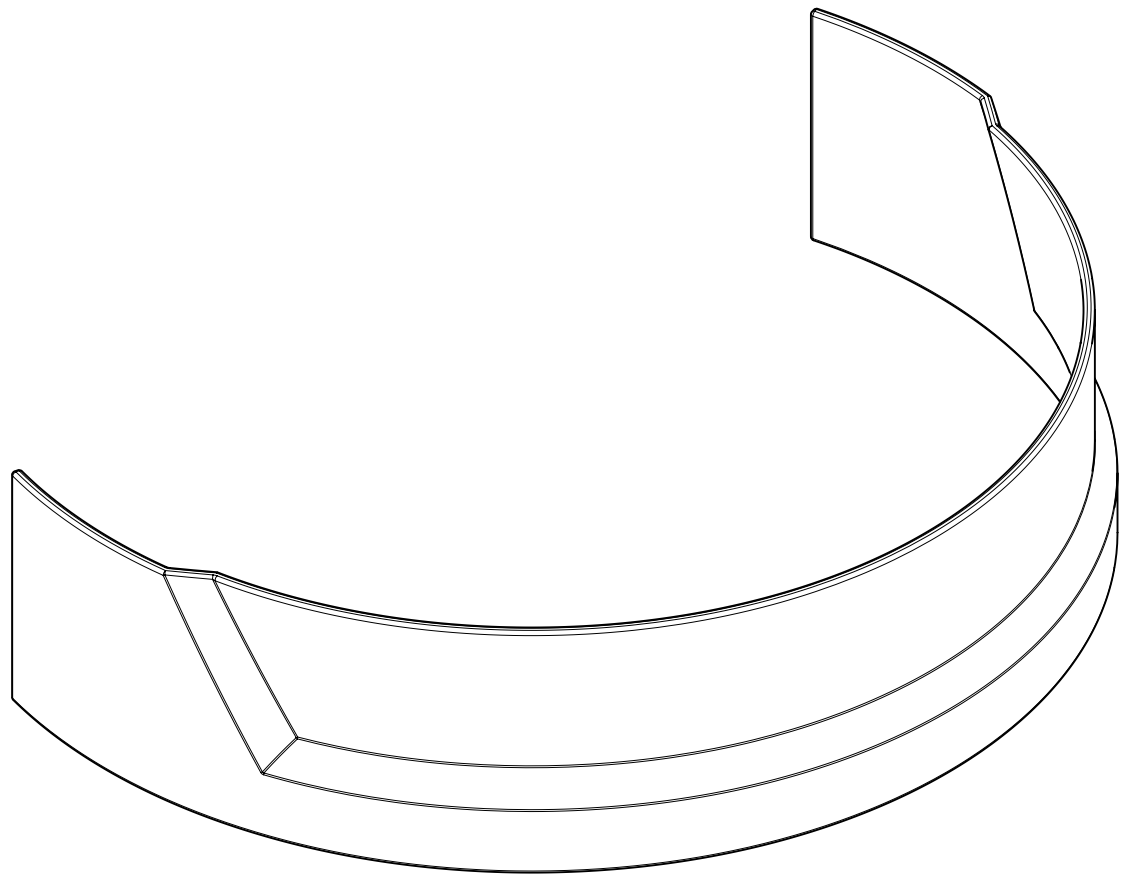


UNIVERSITEIT GENT CAMPUS KORTRIJK	SCALE: 1:1	PART NAME: **Extention Arm B**		NAME: **Rune Vandekerckhove**
		NORM: ISO2768mK	MATERIAL: PP	GROUP: Central Module / DATE: 20/05/2025
		ID PART: Full CAD model V2_scharnier2 inside mirror		**A3**

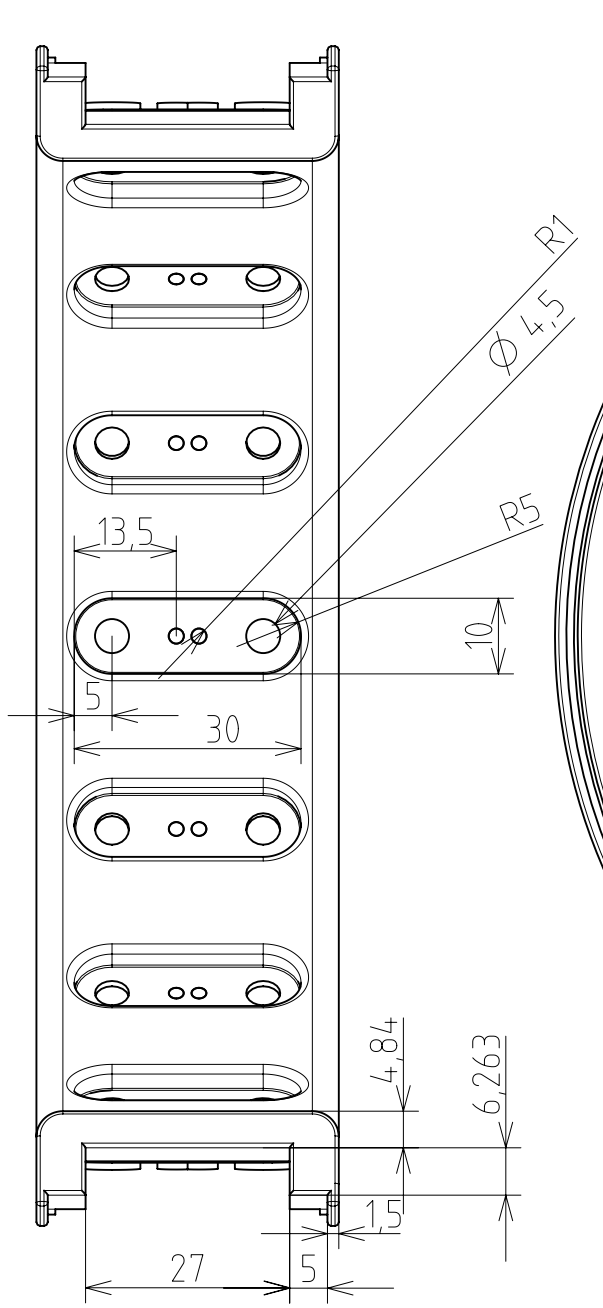


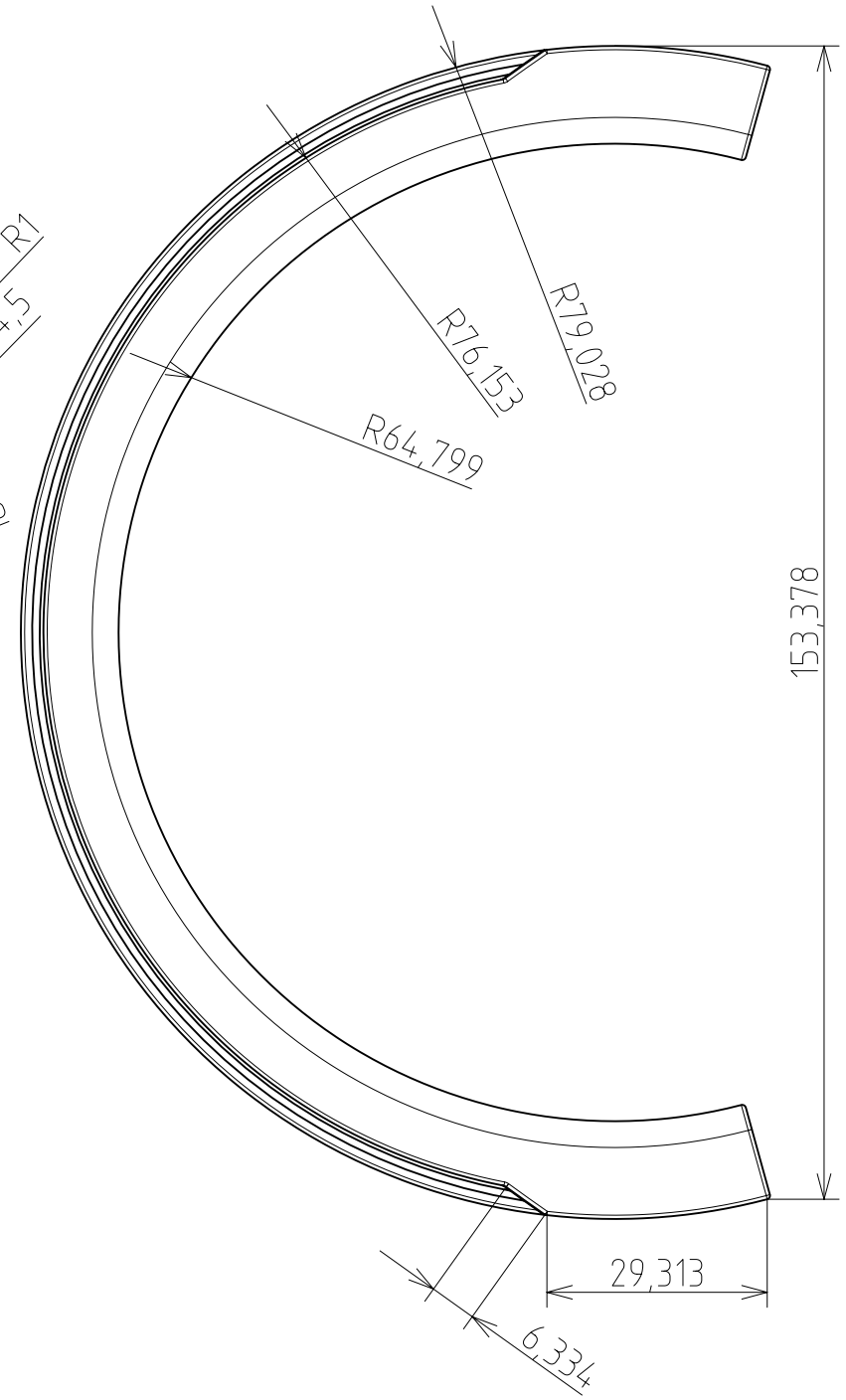


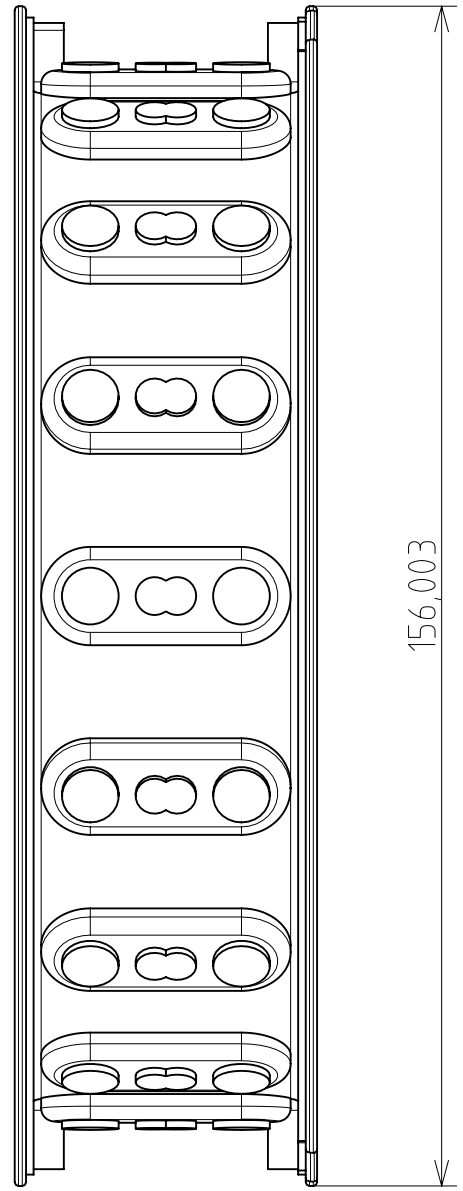


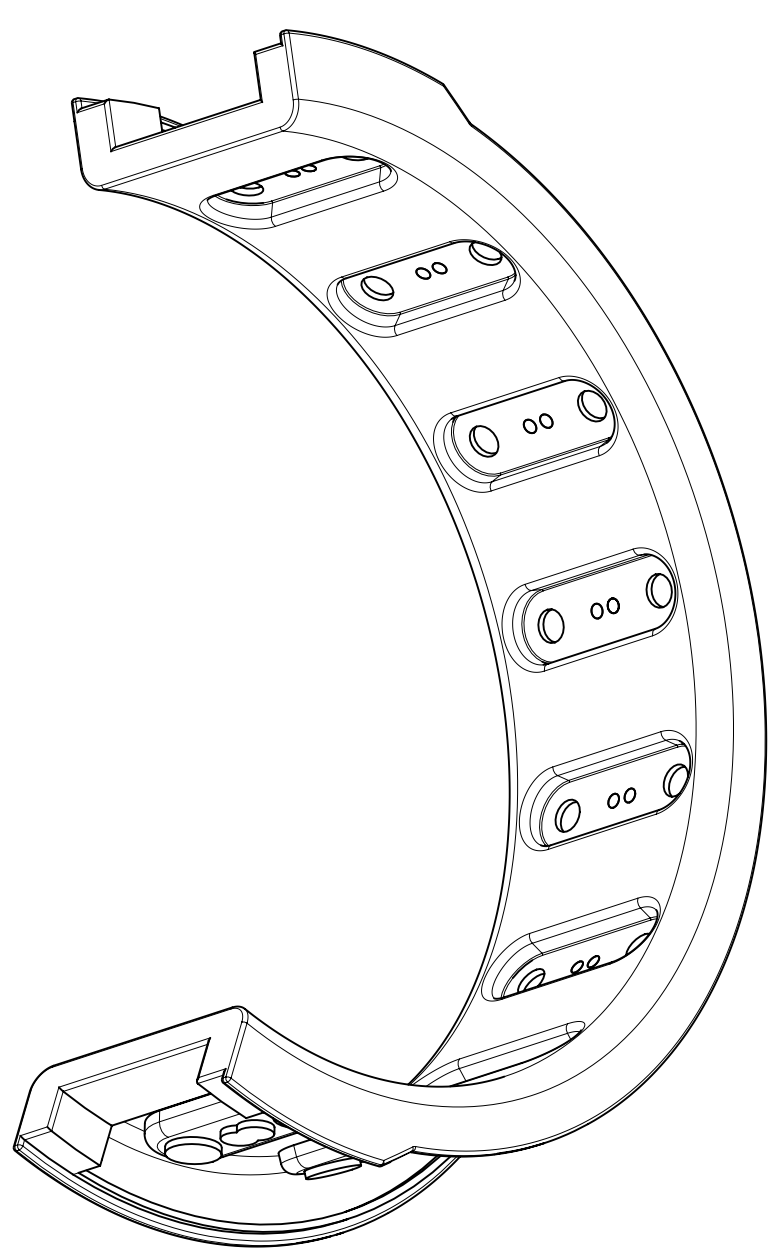


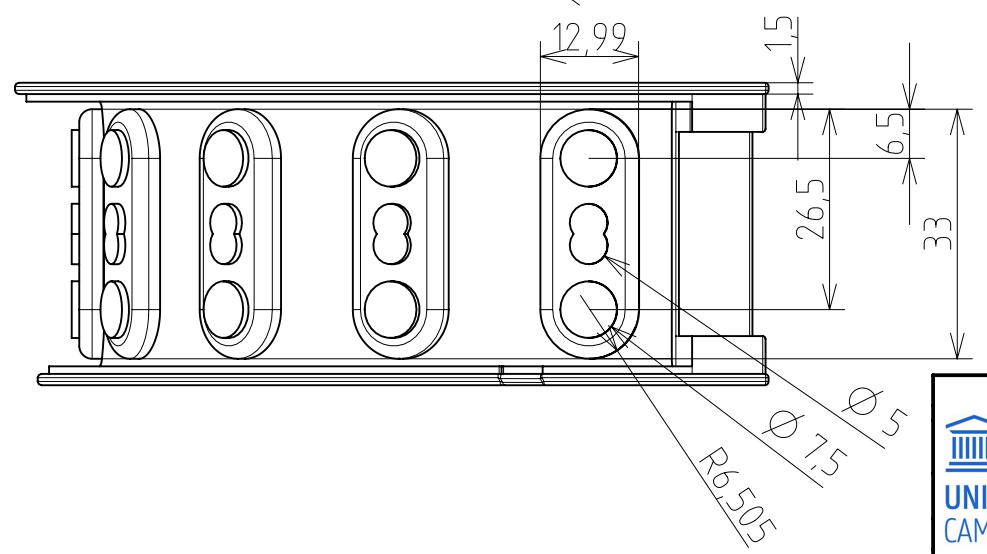
UNIVERSITEIT GENT CAMPUS KORTRIJK	SCALE: 1:1	PART NAME: **Headband Casing**		NAME: **Rune Vandekerckhove**	
		NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Headband	DATE: 20/05/2025
		ID PART: Full CAD model V2_Headband_A_production outside band for drawing			**A3**





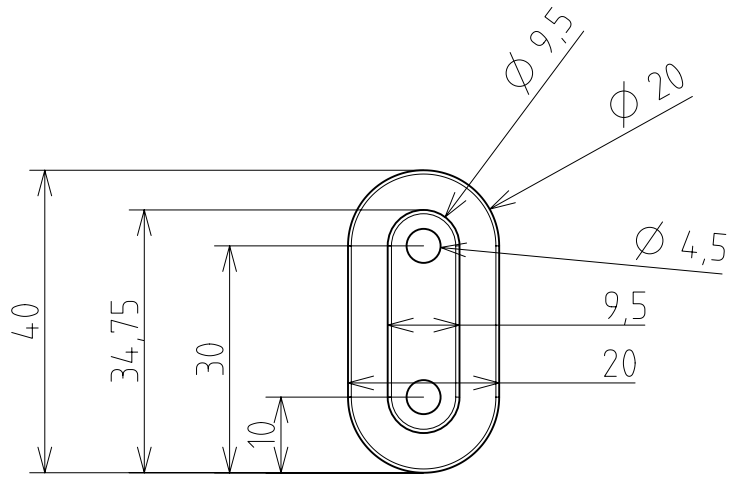


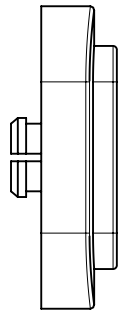


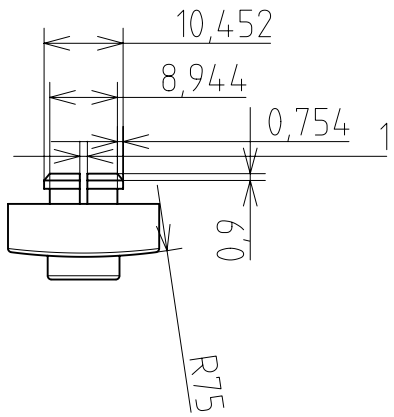


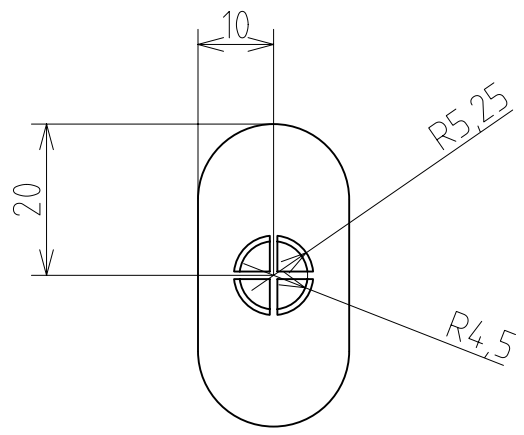
UNIVERSITEIT GENT
CAMPUS KORTRIJK

SCALE:	PART NAME:	NAME:	
1:1	**Headband Inside**	Rune Vandekerckhove	
NORM: ISO2768mK	MATERIAL: PP	GROUP: Headband	DATE: 20/05/2025
ID PART: Full CAD model V2_Headband_B_production inside band			**A3**



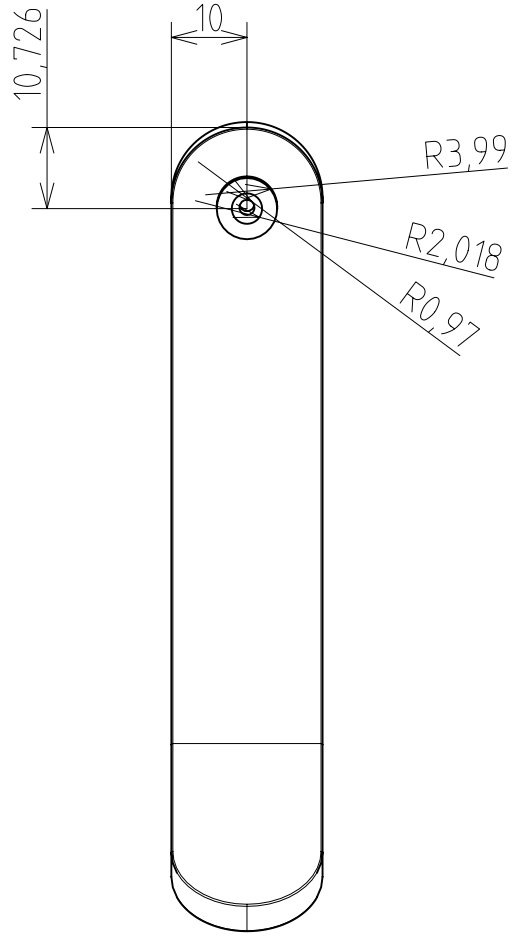


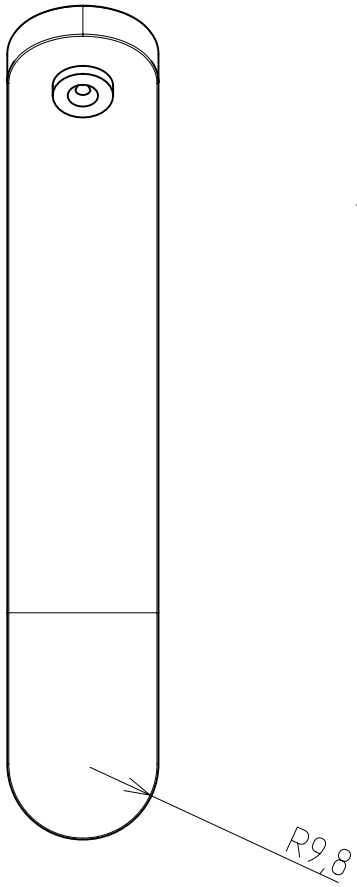


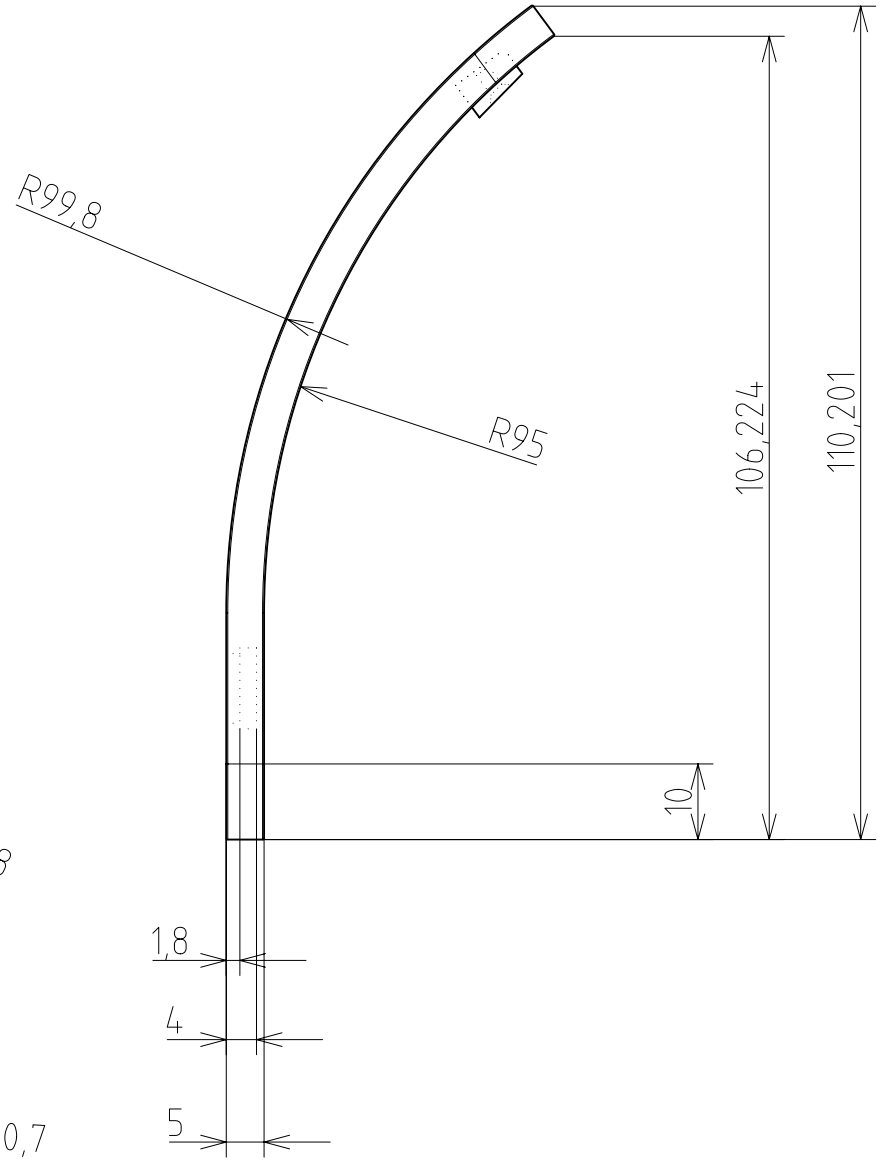


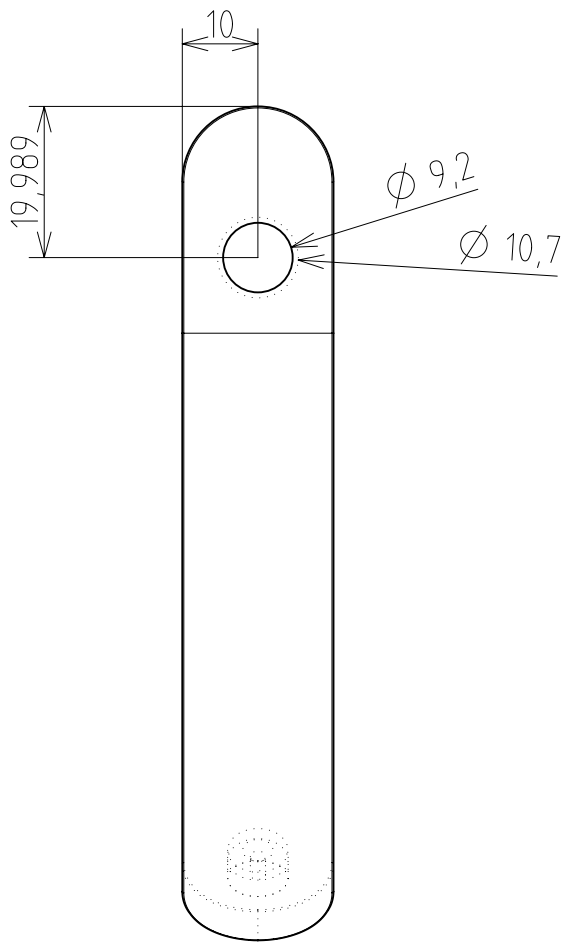
UNIVERSITEIT GENT
CAMPUS KORTRIJK

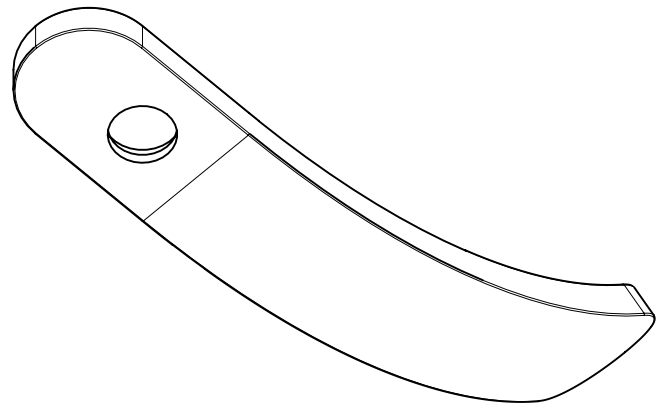
SCALE:	PART NAME:	NAME:	
1:1	Extention Arm Electrode Connectin Port	Rune Vandekerchkhove	
NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Modular Electrodes	DATE: 20/05/2025
ID PART: Full CAD model V2_electrode connector port male v2			A3

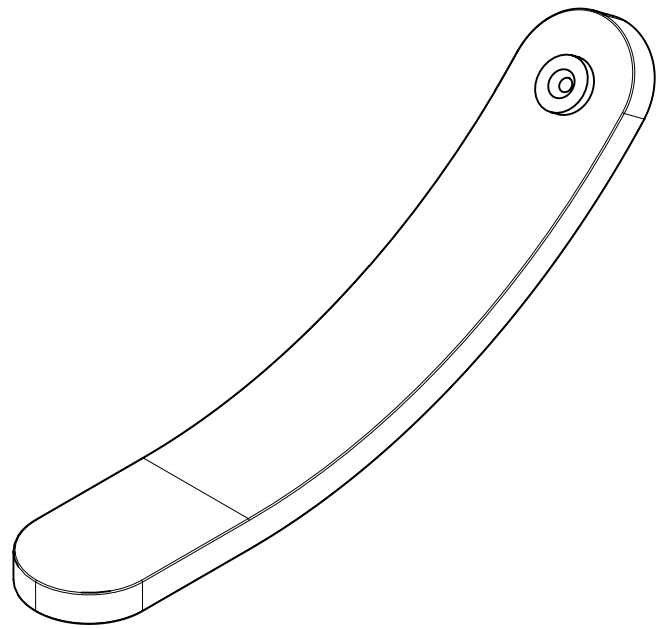












UNIVERSITEIT GENT CAMPUS KORTRIJK	SCALE: 1:1	PART NAME: Electrode Extention Arm Large	NAME: Rune Vandekerckhove	
	NORM: ISO2768mK	MATERIAL: ABS/PC	GROUP: Modular Electrodes	DATE: 20/05/2025
	ID PART: Full CAD model V2_Electrode arm L			A3