User-Centered Design of an Aural Intracortical BCI Communication Interface for a Person with Complete Locked-in Syndrome

By

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Thesis

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Abstract of User-Centered Design of an Aural Intracortical BCI Communication Interface for a Person with Complete Locked-in Syndrome, by Claire Nicolas, ScM, Brown University, May, 2026.

Objective: This research aims to create a new communication system for a person with complete Locked-In Syndrome using an intracortical brain-computer interface. We sought a robust method for BrainGate participant T17, who uses an intracortical BCI to answer yes/no questions.

Methods: We used the Stanford Biodesign methodology as a guiding framework for developing a value-based solution. To best understand the communication needs of our participant we conducted a literature review and observations. We engaged the participant frequently throughout the system design by having them use various minimally viable interface designs and control paradigms, using Wizard-of-Oz testing and usability surveys.

Results: We generated 91 potential solutions in a brainstorming session and narrowed them down to a final Sliding Scale solution that allowed the end-user to select up to 6 targets. By working with T17, we confirmed that the Sliding Scale interface with a scanner-like control paradigm was the most effective method. The new communication interface enabled participant T17 to independently request help with both essential and non-essential activities of daily living.

Conclusions: We successfully tested and implemented a new communication interface for a person with complete Locked-In Syndrome, while documenting one of the first Wizard-of-Oz implementations in the BCI field. We also developed and used unique methods to collect user feedback from people with complex communication needs. These new methods and solutions ultimately enabled the advancement of high-tech, independent communication interfaces with minimal signal acuity.

Chapter 1: Introduction and Background

Brain-computer interfaces (BCIs) are systems that detect and implement human decisions by directly observing the brain (Kawala-Sterniuk et al., 2021). BCIs use invasive or non-invasive neural imaging techniques to collect neural signals (Allison & Krusienski, 2014). The BCI system then analyzes said signals and translates them into control commands of an effector. Closed-loop BCIs constantly monitor neural signals and make instantaneous adjustments to the system output (Jin et al., 2024). The system implements neurofeedback, using real-time visual feedback from effector movement to teach the brain which activity is desirable for effective control of the effector. BCI systems are useful assistive technologies in the communication, computer-control, and mobility domains (Vansteensel & Jarosiewicz, 2020; Wagner et al., 2018; Wolpaw et al., 1991).

BrainGate is a feasibility clinical trial focused on developing intracortical brain-computer interface (iBCI) technologies to restore communication, mobility, and independence to people with severe paralysis resulting from conditions such as Amyotrophic Lateral Sclerosis (ALS), spinal cord injury, or stroke (BrainGate, n.d.; Hochberg, 2025). The system employs surgically implanted intracortical planar microelectrode arrays in the brain's motor cortex. This implant records neural activity associated with the intention to move, which is then decoded in real time by a computer to provide control signals for assistive technologies. Over the past 20 years, approximately 20 people with tetraplegia have enrolled in the BrainGate2 clinical trial. For individuals whose paralysis further involves severely impaired speech, re-establishing effective communication is a high priority.

Intracortical BCIs (iBCIs) provide high-resolution access to the cortical neural networks that activate with the intention to move. Recent iBCI research has demonstrated that real-time decoding algorithms can differentiate neural activity associated with different hand postures or individual finger movements (Jude et al., 2026; Lütschg Espinosa, 2024). For individuals with tetraplegia, an iBCI can decode dozens of different hand movements to provide intuitive neural control of touch-based interfaces through attempted swipes, multi-button mouse clicks, and other hand gestures mapped to useful computer functions (Gross-Lewis et al., 2022; Vargas-Irwin et al., 2025). This rich repertoire of decoded gestures can provide a basis for robust computer interaction that approaches able-bodied levels (Jude et al., 2026). BrainGate study participants with tetraplegia have also achieved rapid onscreen typing by imagining 10-digit finger movements mimicking key presses on a 30-key, three-row keyboard (Lütschg Espinosa, 2024).

While these examples across several study participants have demonstrated the potential of iBCI technology for high-performance communication, accurate decoding of a large suite of hand and finger movements is not always possible. When the technology can decode only a reduced number of intended movements with statistical confidence, familiar computer and typing interfaces become uncontrollable through neural commands. In these cases, it remains unclear how to enable communication with a limited set of accurately decoded attempted movements to navigate a communication interface. This thesis research explores the user-centered design and testing of a novel communication interface developed specifically to address the case in which the number of available neural commands is extremely limited.

Execution of this research was guided by design principles embodied in the Stanford Biodesign framework. User-centered aspects of the process included engagement with a BrainGate trial participant with complete Locked-In Syndrome (CLIS), who evaluated the iBCI in their home environment. These topics are covered in Chapter 2. A principal feature of the design process is developing an understanding of the user's situation and identifying user needs. These aspects of the work are described in Chapter 3. Chapter 4 describes the ensuing "Invent" phase that applies ideation and concept development to move from user needs to the selection of final solution concepts for further development. Chapter 5 describes initial prototype iterations and how final concepts were evaluated and refined through Wizard-of-Oz prototype testing. These prototype activities, along with experiential outcomes from the study participant’s use of the system for communication at home, are described in Chapter 5. Chapter 6 offers a brief overview, discussion, and conclusion.

Chapter 2: General Methods

This research conceived, developed, and evaluated a user interface that enables a person with complete Locked-In Syndrome to communicate via neural signals recorded and decoded by an intracortical BCI. The broad methodologies required for this project are described in this chapter. First, an iterative design process was adopted to provide a guiding methodology for moving from the very broad potential solution space for a communication system in general to the specific solution appropriate for a specific study participant with ALS. The structured interactive design process ensured that we followed user-centered design principles while developing the system. Second, research protocols were inherited from, and constrained by established methods in the BrainGate iBCI trial that enable people with severe disability to engage in iBCI research in their homes. A few relevant aspects of these broad methodologies are described in this section.

2.A. Iterative Design

The iterative design process engages innovators to repeatedly develop, test, and improve on a solution. The iterative design process is frequently used in user experience design and human-computer interaction (Lau, 2024). Ultimately, the iterative design method relies on the frequent and constant repetition of a loop that includes: adaptation, creation, and testing (Figure 2.1) of a specific solution (Halpern, 2021)

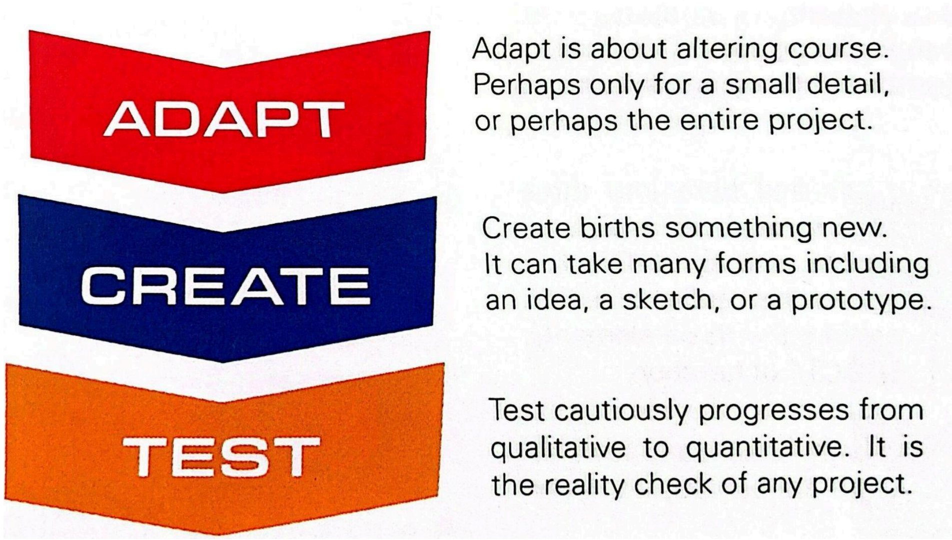


Figure 2.1. Diagram representing the three elements of iteration: adapt, create, and test (Halpern, 2021)

Various guidelines, processes, and methods across industry and academia enable iterative design. For this research, we used the Stanford Biodesign framework, developed specifically for medical technology development.

2.B. Stanford Biodesign

The Stanford Biodesign innovation process was built to ensure that innovations in the biotech field were genuine and important. They describe the Biodesign method as a "practical guide to the new era of global opportunity and value-based innovation in medical technology" (Yock et al., 2015). The Stanford Biodesign method comprises three primary phases: Identify, Invent, and Implement (Figure 2.2). These three phases enable an iterative design and development process that ensures all aspects of a new medical technology are reviewed and planned throughout the framework.

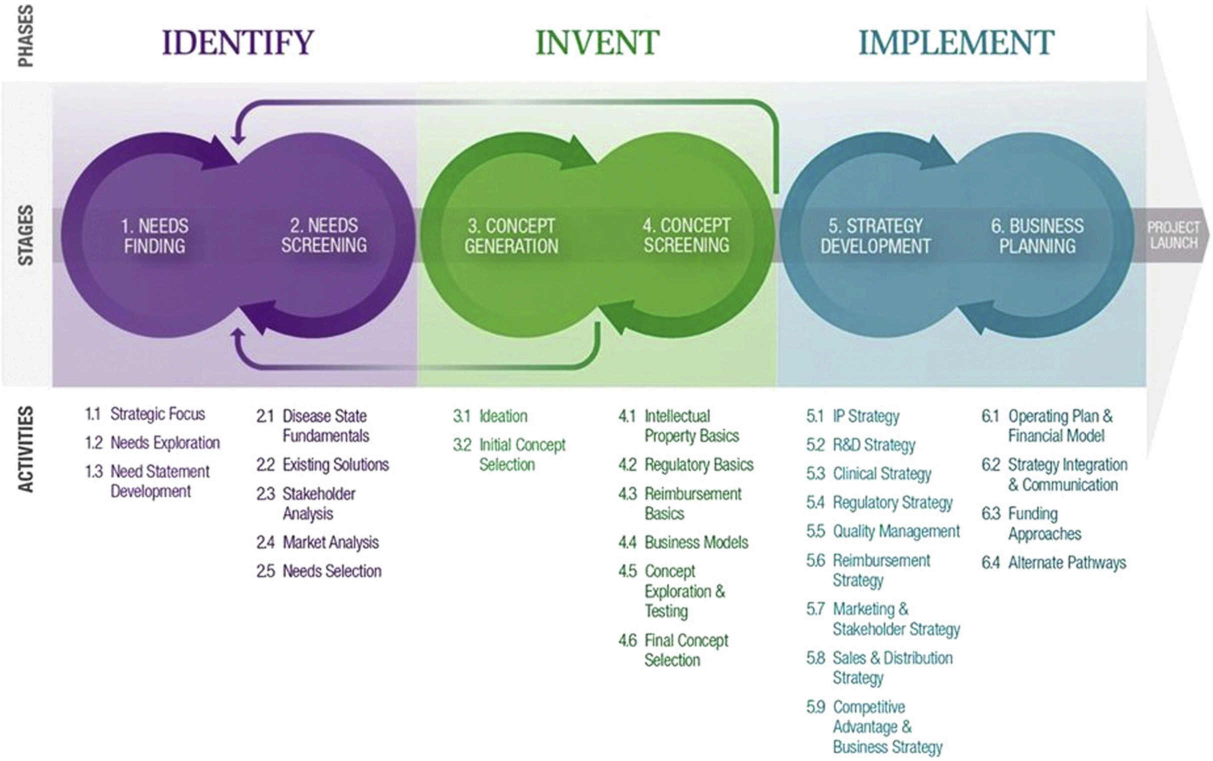


Figure 2.2. The Stanford Biodesign innovation process (Yock et al., 2015)

The Biodesign innovation process engages the researcher in the iterative design process within each and between phases. These can be seen in the figure above (Figure 2.2), with the intra-phase arrows and inter-phase arrows connecting the Invent phase back to the Identify phase. For the sake of this research, we primarily utilized the activities within the Identify and Invent phases of the Biodesign process. Activities and guidelines for following the Stanford Biodesign method can be found in three primary sources:the Biodesign textbook (Yock et al., 2015), the student guide to Biodesign (Stanford Mussallem Center for Biodesign, n.d.), and the official Biodesign website (Leland Stanford Junior University, 2024).

2.C. Engaging a Person with Tetraplegia

The research reported here engaged BrainGate trial participant T17, who was enrolled in the trial according to the inclusion criteria of the BrainGate2 Pilot Clinical trial (www.ClinicalTrials.gov; Identifier: NCT00912041; Caution: Investigational Device. Limited by Federal Law to Investigational Use). The responsible Institutional Review Boards (IRB) granted permission for this study (including Massachusetts General Brigham and Veterans Affairs Providence Healthcare System). At the time of this study, T17 was a 36-year-old male with tetraplegia and complete Locked-In Syndrome (CLIS) due to ALS. T17 had six 64-channel microelectrode arrays (Blackrock Neurotech, Salt Lake City, UT) placed in the ventral premotor cortex, middle precentral gyrus, and dorsal motor cortex (Figure 2.3). The first research session in this study was performed 720 days post-implant, referred to as Trial Day 720.

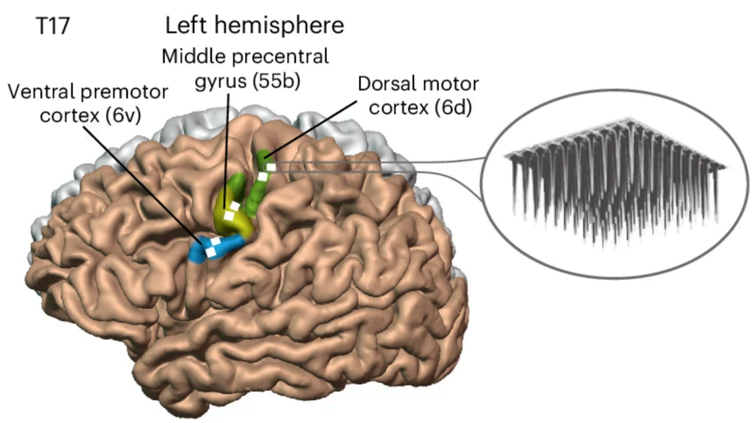


Figure 2.3. T17 microelectrode array placement (from Jude et al., 2026)

T17 relies on the BrainGate system to communicate with the people around him, including his carepartner (CP) and clinicians. Due to the current state of the recorded cortical neural signals, the BrainGate system currently can only accurately decode at most two intended movements with statistical confidence. T17 uses these two attempted movements to answer yes/no questions as prompted by the people he is communicating with.

2.D. Running a Research Session

All research sessions for this thesis were conducted at participant T17's place of residence using the BrainGate iBCI system. During each session, T17 was reclined in bed. Because his vision was variable but often quite poor due to his ALS, T17 relied on a computer speaker that provided aural feedback of the communication system. A Clinical Neurotechnology Research Assistant (CNRA) was present at all sessions to facilitate participant interactions, attach the neural recording devices to the head connectors, ensure proper neural data collection, and confirm the participant's willful engagement in the research. After the recording system was ready, a typical session consisted of multiple "blocks" of data collection in which the participant would complete one of the tasks described below.

Reference Block:

At the start of each session, we ran a reference block to determine the baseline statistics of the recorded neural signals. The reference block consisted of a 3-minute period in which the participant was prompted to remain in a neutral position and not attempt any voluntary movements. The reference block determined electrode-specific neural signal characteristics and defined the baseline neural features to be decoded in future signal processing steps.

Calibration Block:

The calibration blocks collected the model training data required to compute a discrete state decoder for gesture recognition. Each block consisted of an "open-loop" cued task where the participant was cued to attempt predefined gestures 20 times while his cortical signals were simultaneously recorded. The neural signals collected during the block were then down-sampled and processed offline to yield threshold-crossing spike rates and spike-band power features for each recording electrode ("channel"). The extracted features were then used to train a Gaussian Naive Bayes decoder to recognize each intended gesture movement in real-time.

Testing the Communication Interface:

During these blocks, we assessed the various communication interfaces by asking the participant to use the presented communication paradigm to answer specific prompts. This block allowed researchers to determine the participant's ability to control the interface to make sequences of selections or to select specific targets.

Usability Data:

Periodically after working with the system, the participant was asked to answer IRB-approved usability questions pertaining to the participant's experience with the tested interfaces. This user-centered feedback provided input into next iterations of the interface and paradigm designs.

Free Typing Block:

During Free-Typing blocks, the participant was given free rein to use a set interface and control paradigm to communicate freely. During these tasks, researchers facilitated and observed communication between the participant and the people around them.

2.E. Collecting Usability Feedback

When designing any interface for a user, it is imperative to receive their feedback regarding the system. To ensure accurate and frequent participant feedback , we developed an abridged usability survey using questions taken from IRB-approved usability surveys, including NASA TLX, eQUEST 2.0, and the Assistive Technology Assessment (Table 2.1). Usability surveys frequently contained open-ended questions to capture qualitative user feedback. These questions were replaced with pointed yes/no prompts to adapt the data collection method to T17's communication abilities. The pointed questions method of collecting user experience feedback has a probability of biasing the participant's results. However, the method was the most time-efficient manner of receiving feedback and can elicit honest and consistent answers when the user is prompted correctly (Fried-Oken, 2000).

Can you communicate words and phrases efficiently? That is, can you communicate a thought in a timely manner without too many selection steps?				
1-YES I can communicate very efficiently	2-MOSTLY I can communicate relatively efficiently, but a couple of selection steps could be reduced	3-SOMETIMES I can communicate certain phrases in a timely manner, but there are also times when I cannot express phrases efficiently	4-NOT ESPECIALLY It takes a fairly long time and many steps to communicate a single word or phrase	5-DEFINITELY NOT It takes too long and I have to make too many selections to communicate a phrase
Can you accurately select letters and express phrases? That is, can you make selections with minimal errors?				
1-YES I select intended letters and word choices with a high level of accuracy.	2-MOSTLY I select the intended letters and words most of the time, but sometimes I select an unintended character.	3-SOMETIMES I select the intended letters and words at certain times, but I select unintended characters as well.	4-NOT ESPECIALLY Most of the time I select the incorrect letters or phrases. I can rarely select the intended characters.	5-DEFINITELY NOT I cannot accurately select the intended letters or word choices.

<table>
<tr><td colspan="5">Does the device allow you to communicate independently?</td></tr>
<tr><td>1-YES
I can communicate autonomously without relying on another individual.</td><td colspan="3">2-SOMETIMES
I can communicate autonomously without relying on another individual. The device allows me to communicate independently some of the time, but sometimes I need another individual to help me finish words or sentences.</td><td>3-DEFINITELY NOT
I rely on another individual to enable me to communicate.</td></tr>
<tr><td colspan="5">How mentally demanding was the task?</td></tr>
<tr><td>1-VERY DEMANDING</td><td>2- DEMANDING</td><td>3-FAIRLY DEMANDING</td><td>4-SLIGHTLY DEMANDING</td><td>5-NOT DEMANDING</td></tr>
<tr><td colspan="5">How insecure, discouraged, irritated, stressed, and annoyed were you?</td></tr>
<tr><td>1-NOT VERY
Not very insecure, discouraged, irritated, stressed, and annoyed</td><td>2-LESS
Less insecure, discouraged, irritated, stressed, and annoyed</td><td>3-AVERAGE
Average insecure, discouraged, irritated, stressed and annoyed</td><td>4-MORE
More insecure, discouraged, irritated, stressed, and annoyed than usual</td><td>5-VERY
Very insecure, discouraged, irritated, stressed and annoyed</td></tr>
</table>

Table 2.1. Abridged usability survey

After every instance of survey data collection, we would repeat the participant's answers back to him and ask him to confirm if we correctly recorded his answer. If the answer was incorrect, we would prompt the participant to re-answer the question.

For the pointed yes/no questions, the participant was asked if there were any changes, improvements, or comments regarding the system. If the answer was yes, we would list each aspect of the system and ask if he liked or wanted to change that parameter. If he answered yes to that question, we would share the various ways the aspect could be changed and ask the participant if they wanted to change that aspect in that way.

Chapter 3: IDENTIFY

In the adopted Biodesign process, the Identify phase provides a framework for discovering and clarifying the target needs to be addressed before considering possible solutions. It consists of an initial exploration of needs, including review of prior literature and immersive observation of the various stakeholders in the actual clinical environment (section 3A). Potential existing solutions are reviewed and considered, and current options that the stakeholders may already be using or are familiar with. This stage ends with specific needs selections to be advanced to the Invent phase.

3.A. Needs Exploration

Needs exploration is a key aspect of the iterative design process as it helps developers understand the various elements of the problem they are attempting to solve. By completing a thorough needs exploration, we set a strong foundation for our developed solutions. To have a cohesive and comprehensive understanding of the communication needs for a person with CLIS, we took a two-pronged approach: a literature review and user observations.

3.A.i. Literature Review

The literature review examined people with Locked-In Syndrome's sentiments and experiences during communication.

There are important examples of people with LIS sharing their lived experiences. One of the most famous is Jean-Dominique Bauby's memoir "Le Saphandre et le Papillon". Bauby was a journalist and the editor-in-chief at Elle magazine. At 43 years old, Bauby suffered a stroke, leaving him with classic LIS (Crumley, 1997). In his memoir, he recounts his experiences as a person with LIS in a long-term care facility in Paris, France, where he communicated with the world around him by blinking (Bauby, 1997/2007). Throughout his memoir, he shares his thoughts, sentiments, dreams, and encounters. A common theme in this memoir is his inability to communicate independently and his reliance on others to complete activities, including writing this book.

Similar accounts of living with LIS are available through various organizations, including the Association du Locked-In Syndrome (ALIS). These provide testimonies from people living with LIS, helping us better understand their day-to-day experiences and the communication methods used by different individuals.

Their primary means of interaction typically relies on vertical eye movements and blinking (Gaudeul, 2017; Lugo et al., 2015; Nizzi et al., 2012). Initial communication often uses clear "Yes/No" codes or coded alphabets in which an interlocutor recites letters until the patient blinks to select them (Biard & Negre, 2022; Gaudeul, 2017). Advanced technologies can further enhance a person with LIS's sense of agency, including eye-controlled computers, laser pointers, and BCIs (Biard & Negre, 2022).

Despite the severe physical limitations associated with LIS, many people with LIS report a continuous sense of personal identity and a high quality of life, emphasizing that being treated as a person depends heavily on a human environment willing to learn their specific communication methods (Nizzi et al., 2012). Effective communication is considered the ultimate goal of rehabilitation, as it transforms the patient from being viewed as an object into an interpersonal agent capable of expressing their own will (Nizzi et al., 2018; Schnetzer et al., 2023).

3.A.ii. User Observations

While learning about the overall experiences of people with LIS in the literature, we also observed communication between a person with LIS (T17) and those around them during two BrainGate research sessions. During this period, we observed how T17 communicated with members of the BrainGate research team, his carepartner (CP), and various clinicians. These observation periods allowed us to develop a better understanding of the various user needs and the overall need for a robust communication system.

3.A.iii. Needs Statement Development

With the results of our needs exploration, we began developing a needs statement to help focus our future research. We used the Stanford Biodesign template for needs statements to develop the following:

A way to allow a person with complete Locked-In Syndrome to communicate independently with those around them.

3.B. Needs Screening

The needs screening stage of the Biodesign innovation process ensures researchers have an in-depth understanding of the problem space by observing the clinical characteristics, existing solutions, and stakeholder requirements. Ultimately the gathered knowledge will highlight a gap within the space that our research and final needs statement can aim to fill.

3.B.i. Diseased State Fundamentals

Diseased state research focuses on the pathophysiology of the conditions within the pertinent health model (Yock et al., 2015). The information gathered in this section will directly inform our selected needs and solution development.

Locked-In Syndrome

Locked-In Syndrome (LIS) is a rare neurological condition characterized by temporary or chronic tetraplegia, bulbar palsy, and intact cognitive function. (Das et al., 2026; Nilsen et al., 2023). LIS's etiology is mixed, with the most common cause being brainstem strokes, but also includes traumatic brain injuries, and ALS (Lulé et al., 2009; "Qu'est ce que le LIS ?," n.d.). People with LIS are entirely reliant on others to complete activities of daily living (ADLs) and are commonly categorized by their remaining motor function. Due to the rarity of the condition, few population-based studies have examined the prevalence of LIS. Organizational and academic research has reported LIS to affect approximately 500 people in France and 0.7 per 10,000 patients in Dutch nursing homes (Kohnen et al., 2013; "Qu'est ce que le LIS ?," n.d.). There are three main categories of LIS: classic, incomplete, and total LIS (Figure 3.1) (Cleveland Clinic, 2022; Das et al., 2026). Classic LIS presents as total immobility, aside from some eye movements and/or blinking. Incomplete LIS is similar to classic LIS, except for some remaining motor functions. Total, or Complete LIS (CLIS), presents itself as total immobility, including any and all eye movements.

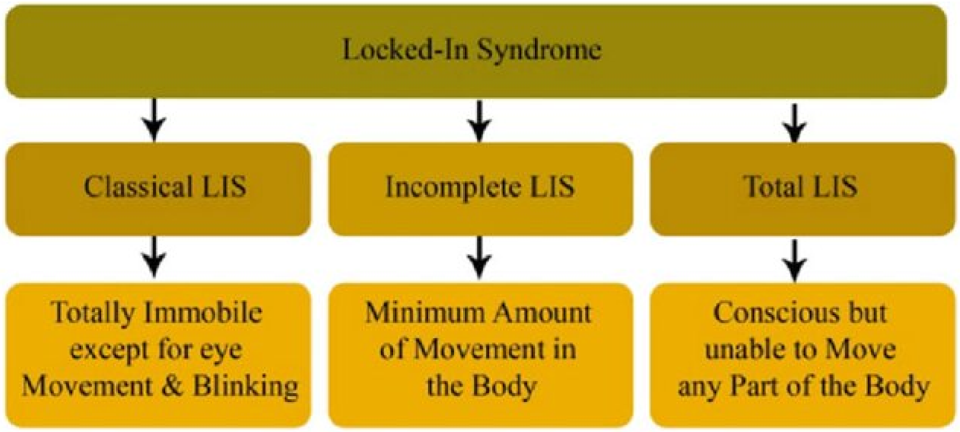


Figure 3.1. Diagram representing the various definitions of LIS
(Mohanchandra et al., 2015)

People with classic or incomplete LIS's consciousness and cortical functions are assessed using blink or eye movement responses to questions. For people with CLIS, neural imaging techniques such as EEG are used to assess consciousness and cortical function (Lesenfants et al., 2018).

Amyotrophic Lateral Sclerosis

Amyotrophic Lateral Sclerosis (ALS) is a neurodegenerative disease that causes loss of voluntary and involuntary muscle control (Mayo Clinic Staff, 2026). ALS causes progressive deterioration of nerve cells throughout the brain and spinal cord, ultimately leading to an inability to perform voluntary movements (Masrori & Van Damme, 2020). As of 2022, ALS affects roughly 33,000 people within the United States (Mehta et al., 2025). There are two main types of ALS: spinal and bulbar onset. Spinal, or traditional ALS, presents as an initial deterioration of nerve cells associated with limb movement. Bulbar ALS presents with initial deterioration of a person's ability to control the muscles involved in speech, resulting in limited or absent speech production, known as dysarthria and anarthria, respectively (Rampello et al., 2016).

3.B.ii. Existing Solutions

Augmentative and alternative communication (AAC) refers to the tools and techniques used to aid communication for people with speech difficulties (American Speech-Language-Hearing Association, n.d.). Common AAC communication methods include scanners, spellers, and core vocabularies. Scanners recite letters or phrases until the AAC-user selects an element. Spellers allow the AAC user to communicate their needs letter by letter. Core vocabulary communication allows users to communicate words or phrases within a predefined core vocabulary. These AAC methods are ultimately combined and tailored to fit the abilities and communication needs of people with speech difficulties with the help of an occupational therapist and speech-language pathologist (American Speech-Language-Hearing Association, n.d.). Depending on the technological requirements of the AAC device, they are categorized into the following groups: low-tech, mid-tech, and high-tech.

BCI-based AACs

For someone with complete LIS, high-tech AACs, such as BCIs, are among the few methods that enable communication. Various BCI-based AACs have been developed, each taking a diverse approach to communication. Our literature review identified three major categories of BCI-based AACs based on the computational complexity of the system: most computationally complex, moderate computational complexity, and least computationally complex.

The more computationally complex AACs utilize deep learning and sophisticated language models to achieve high-throughput communication. Recurrent neural networks (RNNs) are used to translate complex neural trajectories into sequences of phonemes or characters (Card et al., 2024; Jude et al., 2026; Willett et al., 2021). These RNNs are then paired with language models to resolve errors and predict intended sentences from a predefined vocabulary. These systems require massive training datasets and significant computational resources for real-time inference of linguistic probabilities, enabling users to communicate at rates exceeding 30 words per minute.

AACs with moderate computational requirements often involve real-time kinematic tracking and/or multidimensional state classification to control various speller interfaces. These point-and-click interfaces frequently employ kinematic decoders to infer intended cursor velocity in two dimensions, while in parallel using state classifiers to detect discrete "click" intentions, such as an imagined hand squeeze (Nuyujukian et al., 2018). Some systems solely rely on multi-dimensional classification of detected discrete gesture intentions to control speller interfaces, notably a QWERTY keyboard (Figure 3.2) (Bacher et al., 2015; Lütschg Espinosa, 2024).

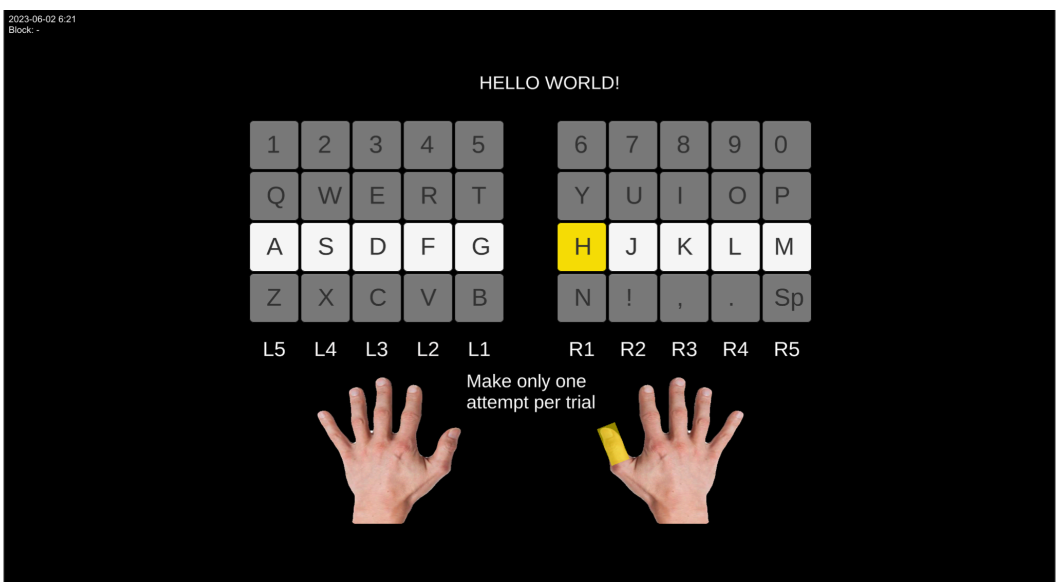


Figure 3.2. Example QWERTY-keyboard speller interface for iBCI
(Lutschg-Espinosa et al., 2024)

Other BCI-based AAC spellers have attempted to improve the user's experience by modifying the individual letter locations and selection methods to work best with the system's requirements (Bacher et al., 2015; Müller et al., 2008; Pandarinath et al., 2017). The Hex-o-Spell and Radial Keyboards are two examples of BCI-based spellers with optimized interfaces to minimize cursor travel distance while maintaining standard selection algorithms (Figure 3.3).

a. b.

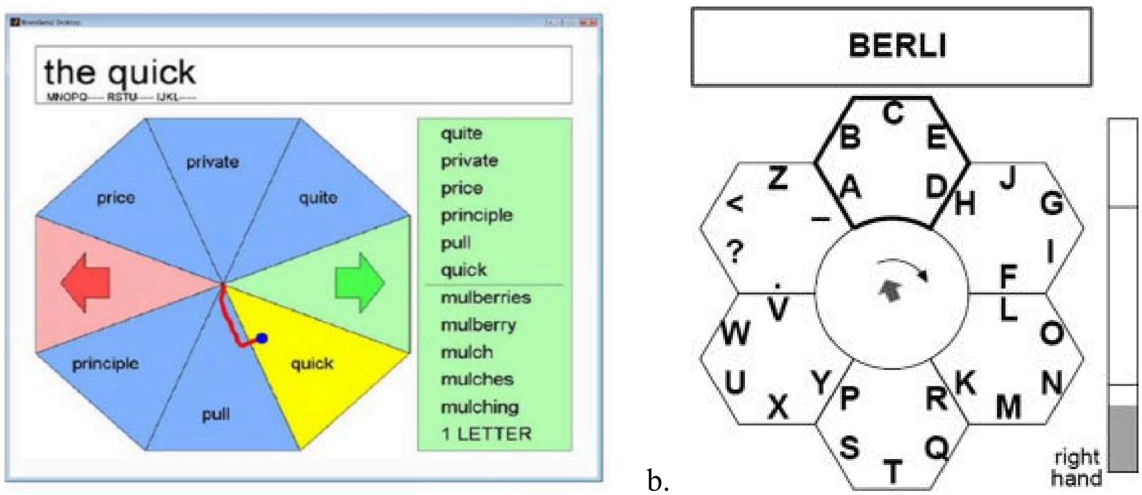
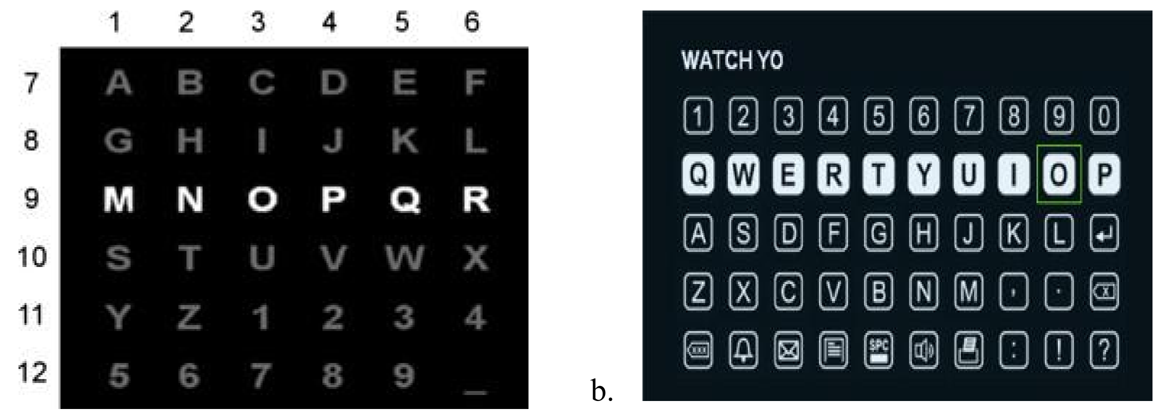


Figure 3.3. Various onscreen keyboard designs for BCI control.

(a) Non-QWERTY Radial Keyboard -keyboard speller interface for BCI control (from Bacher et al., 2015). (b) Hex-o-Spell letter interface (Muller et al., 2008).

Point-and-click and gesture-based systems use a large suite of attempted movements for interface control. To accurately decode the large suite of attempted movements, the decoders require robust neural features and, in turn, a higher signal-to-noise ratio within the neural signals.

The BCI-based AACs with the lowest computational requirements frequently rely on binary decoders, Event-Related Potentials (ERPs) or Steady-State Visual Evoked Potentials (SSVEPs). Initial versions of ERP-based speller, such as the P300 matrix speller, identify target letters by detecting neural activity when a user's chosen character is highlighted during random row and column flashes (Figure 3.4.a) (Cecotti, 2011).



a. b.

Figure 3.4. Example of scanner-based speller interfaces for BCI control.
(a) A typical P300 speller interface. (b) IntendiX interface. (Cecotti, 2011)

Variations of the P300 matrix speller have been developed and deployed to improve communication, such as the intendiX (Figure 3.4.b), and Rapid Serial Visual Presentation (RSVP) (Cecotti, 2011; Peters et al., 2025). SSVEP-based spellers require users to focus on visual stimuli flickering at distinct frequencies to navigate virtual keyboards or selection menus (Cecotti, 2011). Slow Cortical Potentials (SCP) interfaces allow completely paralyzed patients to select letters by regulating their brain's electrical shifts to choose between two "banks" of the alphabet (Birbaumer et al., 1999). Within these low computational systems, we frequently see the use of binary or trinary state decoders, which can decode fewer discrete neural states. These systems may take longer to control, but are more resilient against poor neural signal acuity.

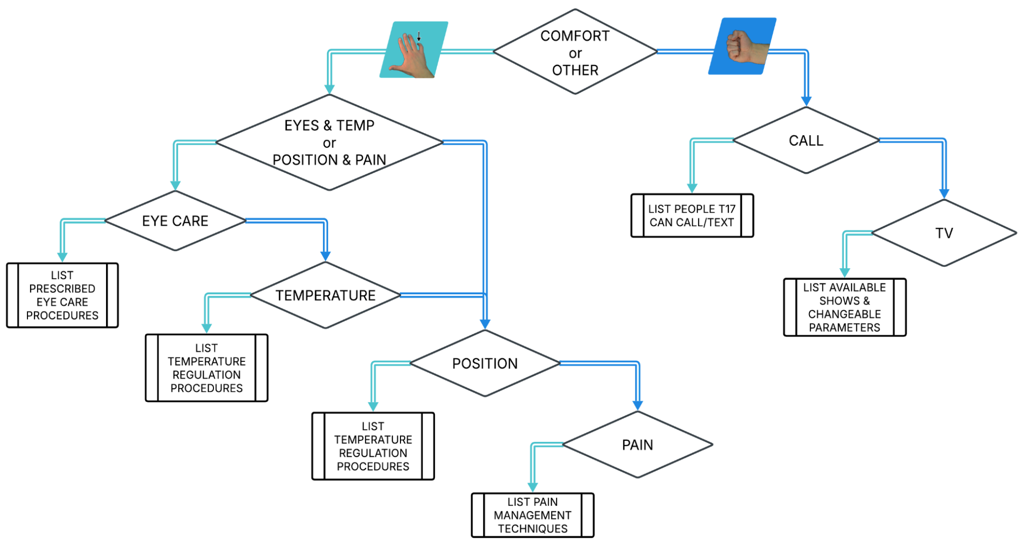
Ultimately, most BCI-based AAC systems rely on visual stimulus or a visual interface to communicate system changes. Alternative modalities and specialized interface designs provide communication options for users with diverse sensory impairments. Tactile spellers provide a gaze-independent option by applying mechanical taps to the user's fingertips, requiring them to count taps on a target finger to make a selection (Brouwer & Van Erp, 2010; van der Waal et al., 2012). Auditory spellers similarly allow for communication without visual input by representing keyboard elements with unique sounds or spatial locations (Kübler et al., 2009). These specialized interfaces allow for users with various sensory impairments to use BCI-based AACs as their method of communication.

T17's current communication method

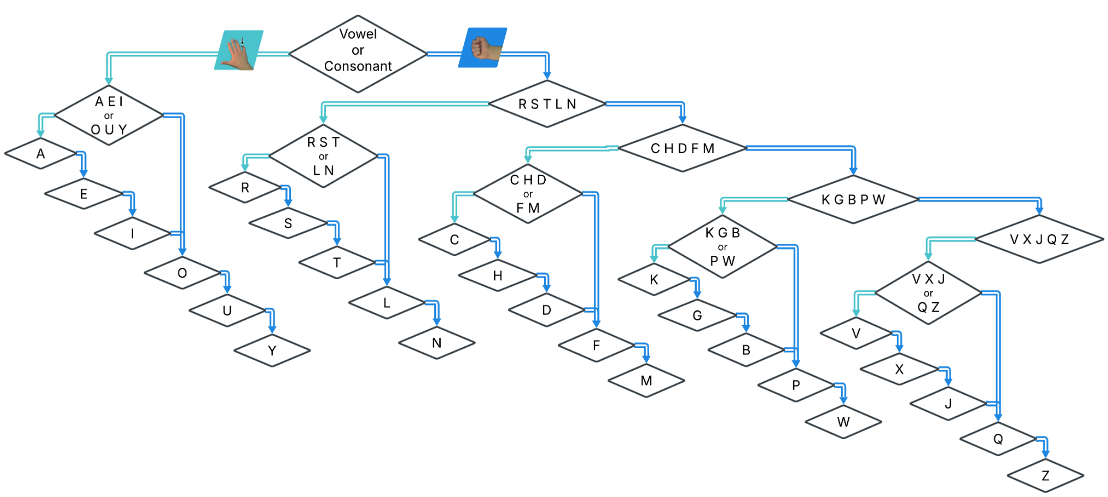
Due to T17 presenting with CLIS, he and his CP use the BrainGate BCI system to communicate with each other. Since joining the clinical trial, T17 has used the BrainGate system to control QWERTY-based spellers with success (Jude et al., 2026; Lütschg Espinosa, 2024). However, since implantation, there has been a degradation in recorded neural signals, causing the previously tested systems to be unusable for T17. Instead, T17 and his CP use a three-state Gaussian Naive Bayes decoder (Do_Nothing, Gesture_1, Gesture_2) in a cued task structure to communicate. This allows T17 to answer yes/no questions by attempting to perform one gesture or another. The iBCI then attempts to decode the neural signals to identify which response is being issued; when answering yes/no questions, T17 attempts Gesture_1 to signify "Yes" and Gesture_2 to signify "No". However, due to poor decoding, T17 must repeat this attempt twice in a row to confirm his answer. T17 and his CP use the same control paradigm in various communication scenarios, such as communication of basic needs and letter-by-letter spelling.

Using Yes/No responses as Left-or-Right responses, T17 and his CP work together to determine the element T17 wishes to communicate using either vocabulary or letter banks, depending on the communication scenario (Figure 3.5.a). When T17 is attempting to communicate basic needs, the carepartner will guide T17 through a core vocabulary of needs, organized into a nested structure based on need type, until a single need is identified (Figure 3.5.b). They use the core vocabulary system as a quick and easy method of determining what care T17 requires. If T17 wishes to communicate something that is not within the core needs vocabulary, then T17 can communicate using an alphabet organized into a hierarchy of groups of letters, which, at the end of the hierarchy, result in the identification of a single letter (Figure 3.5.c).

a.



b.



c.

Figure 3.5. T17's default communication method was complex.

(a) T17's communication methods based on the communication scenario. (b) T17's default communication of core needs. (c) T17's hierarchical organization of letters

This method of communication was complex and required in-depth knowledge of the selection hierarchy and of the gesture decoding. Further, because each selection relied on imperfect neural decoding, there was a relatively high probability of an erroneous selection that could go undetected until a nonsensical sequence of letters or needs was evident. The burden of the carepartner to track letter selections and possible error corrections was remarkably burdensome and complex.

3.B.iii. Stakeholder Analysis

To best understand the stakeholders involved in caring for and communicating with people with LIS, we observed the cycles of care across the various etiologies of LIS. This analysis, along with our prior research, enabled us to define three major stakeholder groups: communicators, caregivers, and researchers.

Communicators

Communicators, also known as the system's end-user, are the people who use our solution to communicate with others in the room. In our case, the end user is T17, a person with CLIS. In modern care models, people with CLIS are recognized as proactive partners rather than passive recipients of care. They use various communication methods to share their needs and support their health goals (Cleveland Clinic, 2022; Lulé et al., 2009). People with CLIS have complex care needs and commonly require respiratory, nutritional, continence, and positioning support (Farr et al., 2021; Miller et al., 2009). The support can come in the form of medical devices and clinical procedures: tracheostomy tubes, suction machines, ventilators, cough assist devices, percutaneous endoscopic gastrostomy (PEG) tubes, gastrojejunal (j-tubes) tubes, catheters, support wedges, and splints (Farr et al., 2021; "Le parcours hospitalier de la personne LIS," n.d.; Miller et al., 2009; Shirley Ryan Ability Lab, n.d.). All supporting devices and systems need to be meticulously managed by caregivers.

Caregivers

Caregivers are the people who provide medical and personal care to another person, in this case, someone with CLIS. There are two primary types of caregivers: clinicians and carepartners (CPs).

Clinicians are healthcare professionals who provide clinical services, including doctors, nurses, and therapists. Clinicians provide the specialized expertise required to navigate the medically complex landscape of LIS, beginning with acute stabilization by neurologists and intensive care specialists who manage life-threatening complications ("Le parcours hospitalier de la personne LIS," n.d.). As the journey transitions to rehabilitation, a multidisciplinary team led by physical, occupational, speech-language, and respiratory therapists aims to maximize residual function (Farr et al., 2021; Miller et al., 2009; Shirley Ryan Ability Lab, n.d.). These clinicians manage critical needs such as respiratory function via tracheostomy care, nutrition via gastrostomy tubes, and communication via AACs. Most of these clinicians will vary in how often they interact with patients, from daily to monthly to every few months. Accurate communication among clinicians, carepartners, and people with LIS is extremely important and can be more difficult when using AAC (Morris et al., 2013).

Carepartners (CPs), also known as caregivers, are patients' friends and family who help care for them day to day (Bennett et al., 2017). Their role is multifaceted, encompassing intensive support with activities of daily living (ADLs), coordination of medical appointments, and management of medications. Beyond physical assistance, carepartners act as vital communication bridges and advocates, often translating the patient's responses for clinicians and ensuring the patient's best interests are upheld (Shirley Ryan Ability Lab, n.d.). Because the carepartner's role often evolves and intensifies over time, they require mutual education alongside the patient to manage specialized equipment and prevent complications (Bennett et al., 2017; Shirley Ryan Ability Lab, n.d.).

BrainGate researchers

BrainGate research sessions are conducted by a varied team of researchers, including software engineers, graduate and undergraduate students, CNRAs, and clinicians. All of these researchers collaborate and use the BrainGate iBCI system to answer research questions within the BCI space. To allow researchers to use the BrainGate system while T17 continues to communicate, it was imperative that we understood the BrainGate system and the researchers' requirements.

We were able to define both the design and system requirements by interacting with and observing various researchers (Table 3.1).

System requirements	● BRAND compatible ● Does not interfere with other data collection efforts ● Editable parameters
Researcher Needs	● Records decoder & communication output in an easy format ● Shares and records decoder accuracy ● Offers visual feedback on system status ● Allows the end-user to consent to session recording ● Allows for participant feedback ● Gives insight into participant sentiments ● Offers session and block information ● Does not interfere with session debugging

Table 3.1. BrainGate researchers and system requirements

In summary, the stakeholder analysis revealed the interconnected roles of communicators, caregivers, and researchers in supporting individuals with LIS. By understanding the unique needs, challenges, and contributions of each group, we were able to develop comprehensive design and system requirements that address the realities of all stakeholders. This holistic approach ensures our solutions are better aligned with the lived experiences of people with CLIS and those who support them, ultimately promoting more effective care and communication.

3.C. Needs Selection

The prior section allowed us to uncover stakeholder and system needs that the interface must try to meet. We notice that some needs overlap between groups, and most needs follow the usability principles of user interface design as set forth by Nielsen (Nielsen, 1994). Duplicate needs were filtered and condensed for ease of analysis using the Nielsen usability heuristics as the baseline requirements. Within the final needs, some are perceived as more important than others. To analyze the importance of each stakeholder and system need, we used the pairwise comparison chart to determine the ranked importance of each need.

3.C.i. Methods

We used the pairwise comparison chart, which utilizes one-on-one comparisons to determine the hierarchy of needs (Wind & Saaty, 1980). In this process, we assess each pair of needs to determine the degree to which one is more important than the other, using a 3-point scale where -1 indicates lesser importance, 0 indicates equal importance, and 1 indicates greater importance. These qualitative judgments are organized into a reciprocal matrix and transformed into a largest-eigenvalue problem. We then receive a priority vector where the values (or weights) represent the perceived importance of each need. The greater the weight, the more important the need.

3.C.ii. Results

Need Types	Requirement	Weight
Communicator Needs	Stable and consistent decoding	4
	Primarily non-visual cues	2
	Requires minimal cognitive load	3
	Can use independently	5
	Can use for extended periods	1
Communicatee Needs	Offers Visual feedback	4
	Easy to understand	2
	Tracks users prior statements	3
	Some ability to "control" the conversation	1
	Instills confidence in T17's arousal	5
	Allows for participant consent	6
Design Needs	Primarily uses non-visual cues	4
	Offers visibility of system status	9
	Uses familiar mapping	3
	User "exit"	5
	Standardized interface	7
	Robust system (preventing errors)	8
	Minimal user memory load	6
	Flexible use	1
	Minimalist design	2

Table 3.2. Weights of user needs and design needs

After completing the pairwise comparison chart, we determined that the most important needs were independent use, assurance in user attempts, and robust system for the communicator, caregivers, and design needs, respectively. The collected weights will also allow us to more accurately analyze the efficacy of the developed concepts in fulfilling the system requirements.

3.D. Final Needs Statement

After completing the IDENTIFY phase of the Biodesign framework, we updated our written needs statement to best match the user needs and system requirements. The final statement followed the Stanford Biodesign's need statement template (Yock et al., 2015):

A way to facilitate communication of needs in people with complete Locked-In Syndrome that utilizes minimal neural features and external factors.

Chapter 4: INVENT

After considering the problem space and clarifying stakeholders and their needs in the IDENTIFY phase, we advanced to the INVENT stage of the Biodesign innovation process. This phase determines some of the possible ways to address the needs identified with the goal of conceiving and then paring down a set of candidate concepts for further exploration. As described below, this begins with broad brainstorming, developing concepts, and then rigorously identifying final concept(s) for actual implementation and assessment in the Prototyping phase to follow.

4.A. Initial Brainstorming

4.A.i. Methods

A good ideation process always starts with a brainstorming session; to include a variety of stakeholders, we conducted a rapid ideation session with stakeholders within the Hochberg Laboratory at Brown University.

To ensure that all people knew how a brainstorming session worked, we introduced the concept of brainstorming, and specifically, rapid ideation. We then actively engaged team members in an introductory brainstorming activity, allowing them to think in new and unconventional ways. The team members were then given a chance to discuss their sentiments and ask clarifying questions about the rapid ideation process before delving into the second brainstorming activity.

Rapid Ideation for CLIS

The second brainstorming activity focused on developing unique solutions to our needs statement. Before beginning the activity, team members were given an overview of the problem space, the system requirements, potential use cases, and constraints (Figure 4.1). Each team member was then told to generate 15 diverse and unique solutions that would allow a person with CLIS to communicate with a person with the people around them.

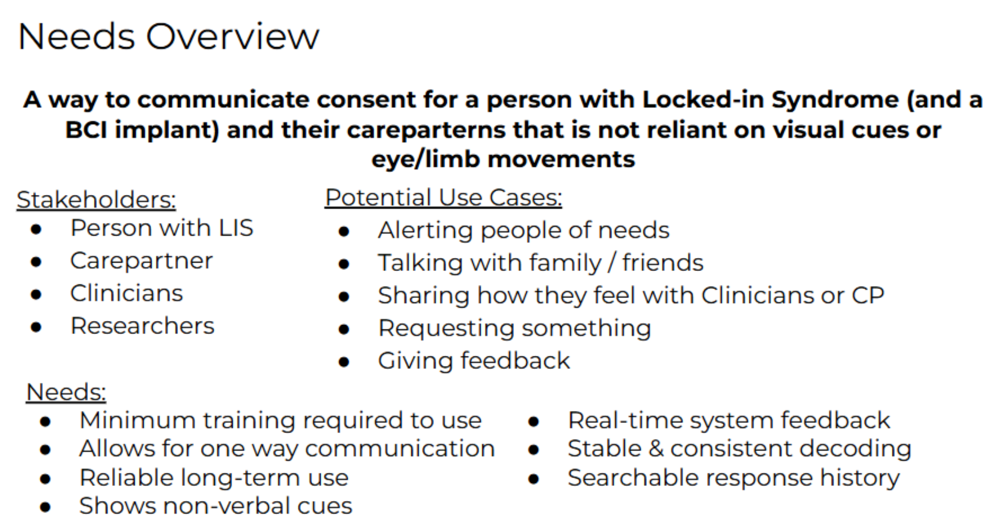


Figure 4.1. Screenshots of the Google Slides developed for the rapid ideation for the CLIS task

Mind-mapping & collaboration

After the brainstorming task, team members were asked to share their five favorite solutions with the rest of the team. During the discussion period, we facilitated communication among team members to foster the creation of new collaborative solutions. All developed solutions were added to a Miro board, and then the team members were asked to group and connect the various solutions to create a mind map.

4.A.ii. Results

We had 6 people attend the brainstorming session, including researchers, clinicians, and research assistants. The attending team members generated 91 solutions during the second brainstorming activity. The solutions were then filtered for duplicates and categorized as follows: Speller interfaces, closed-loop feedback, non-speller interfaces, and decoder methods.

Speller Interface Solutions

The speller category consists of all solutions in which the user writes words by selecting individual letters. These spellers use a variety of decoding methods and interface setups, including hierarchical structures, QWERTY keyboards, and radial keyboards.

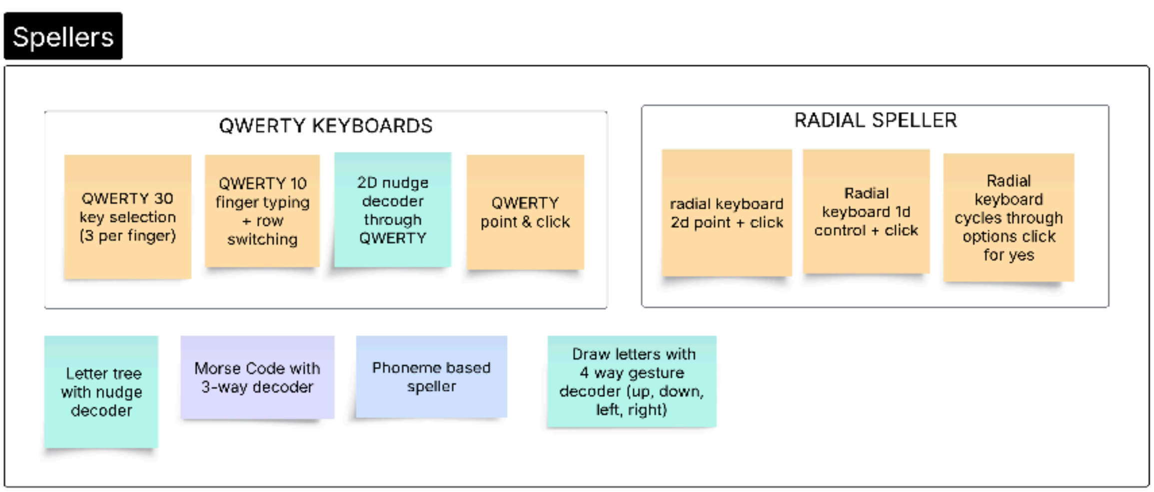


Figure 4.2. Brainstorming solutions: speller interfaces

Closed-Loop Feedback Solutions

The closed-loop feedback solutions focus on the feedback provided to the end-user during interface control. Within the category, there were solutions that offered visual, auditory, or tactile feedback to alert the end-user to the current system status and ultimately reduce the required cognitive load to control the interface. We also find biofeedback-related solutions that collect and display additional biosignals, such as hormone levels and heart rate, to help the user control their bodily processes, with the hope of ultimately improving their control of the system (Frank et al., 2010).

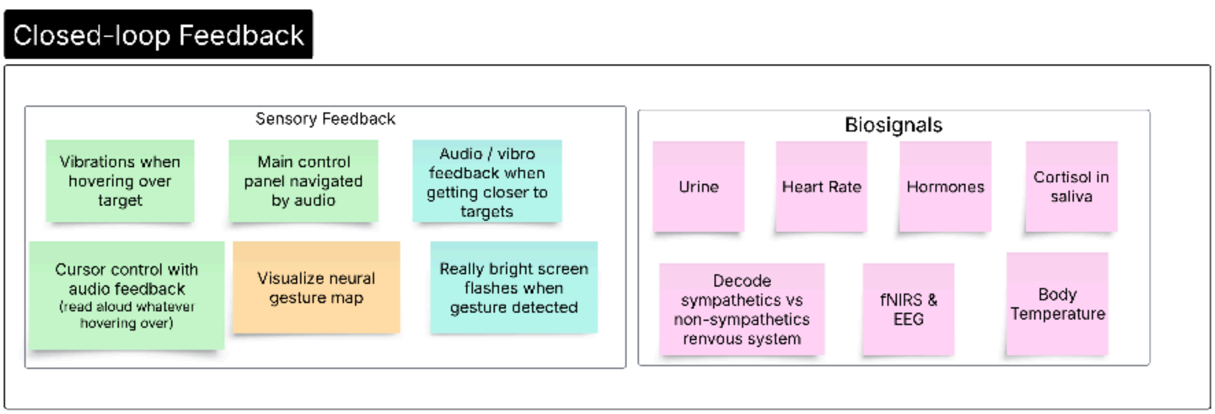


Figure 4.3. Brainstorming solutions: closed-loop feedback.

Non-Speller Interface Solutions

We worked to identify several non-speller-based solutions; these interfaces were categorized as follows: vocabulary-based communication, pager systems, indirect communication, and Sliding Scales.

The vocabulary-based communication category consisted of all solutions that relied on a predetermined set of words or sentences that the user could use to communicate. In these cases, the core vocabulary would be customizable and would consist of the end-user's most frequently used terms, phrases, and sentences.

The paging solutions were those in which the end-user controls a binary effector to alert caregivers of the end-user's desire to communicate. These solutions would allow a user to request help or assistance from people outside of their general vicinity. The effectors used to alert other users varied greatly, including: a call-light, a fan, a train on tracks, and a general alerting system.

Indirect communication solutions are systems that leverage emotional connections to various stimuli. In the color scale solution, the end-user chooses colors they believe best signify the need they are trying to communicate. For example, the user may select an aqua blue when requesting water. These solutions are creative and do not rely on traditional writing systems to communicate.

The sliding-scale solutions are systems in which a user is given a set of targets they can select along a specific axis. These scales frequently fall between two extremes, offering a gradient of responses. A common use of Sliding Scales includes the pain scale used in clinical settings (Frampton & Hughes-Webb, 2011).

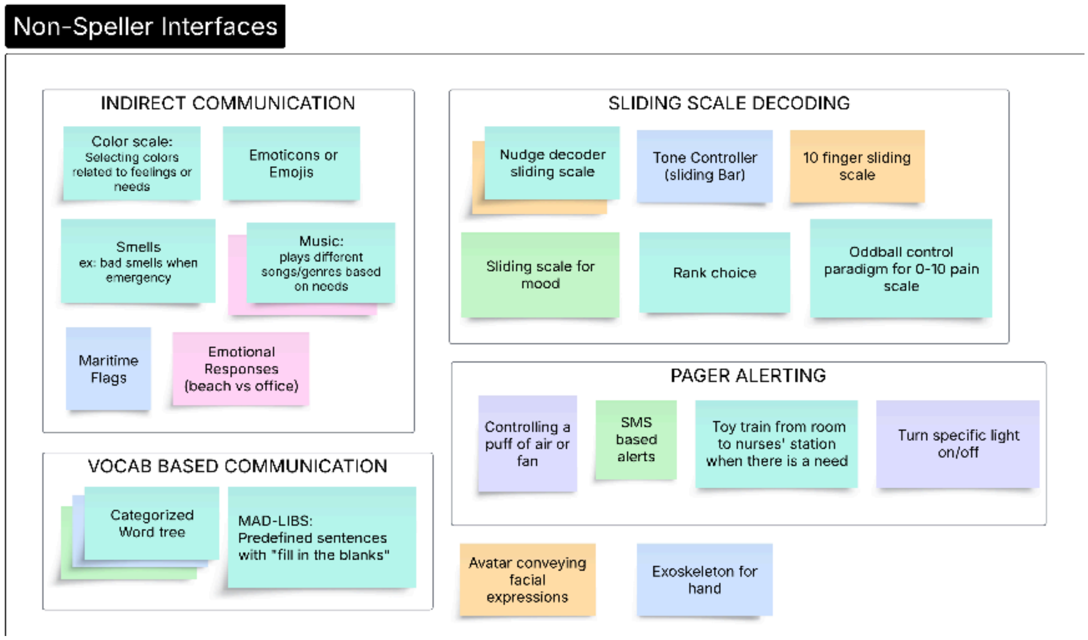


Figure 4.4. Brainstorming solutions: non-speller interfaces.

Decoder Methods Solutions

Various solutions related to the decoder methods used during control. Some solutions simply focused on the type of decoder being used, discrete, kinematic, or a combination of both. We also observed what was considered a “nudge” decoder, in which the user inches along a fixed axis using a specific gesture. We also focused on novel decoder imageries that could potentially lead to more robust decoders. These can also be combined with additional signal collection to improve the system. We also determined that we could use binary decoders, paired with additional context clues, to expand the user's selection options. These solutions are similar to P300 speller paradigms.

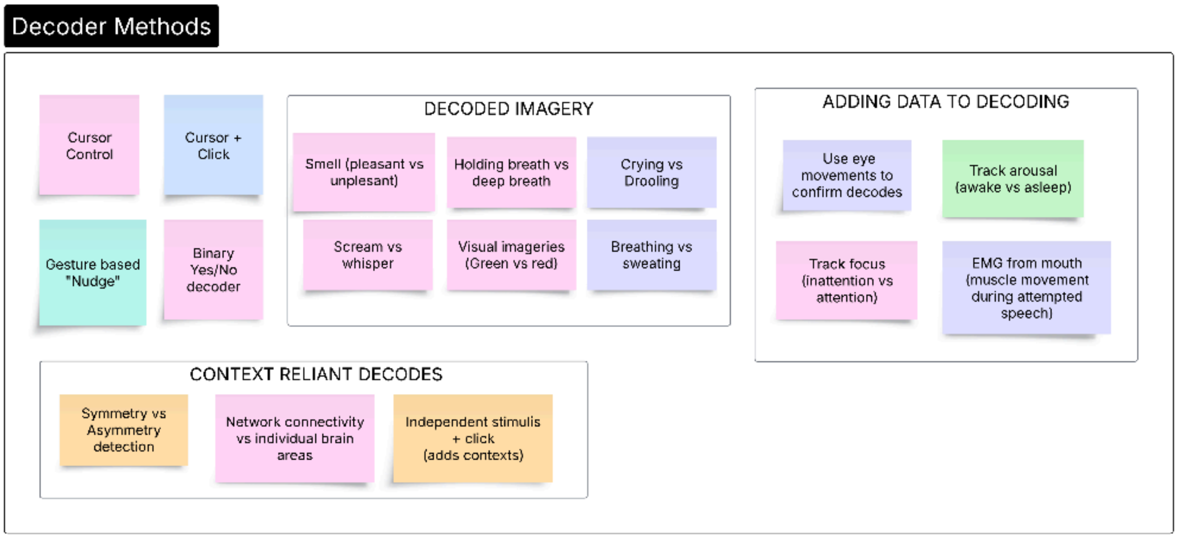


Figure 4.5. Brainstorming solutions: decoder methods

4.B. Concept Screening

4.B.i. Viable Concept Selection

With the solutions categorized, we compared each individual solution against our constraints, which include reproducibility, ease of creation, accessibility, and feasibility. This initial pass allowed us to eliminate all solutions that were not feasible within the time constraints and would not meet our system needs.

Constraints	
Easy to control	Requires minimal neural signals to manipulate (fewer than 4 discrete gestures) AND/OR no physical abilities
Quick to use	The interface is faster for communicating needs than other traditional methods
Easy to understand	People with minimal experience with BCIs can understand what is happening
Customizable	Users can customize how and what is presented
Independently	A person with LIS can communicate independently

controllable	
Feasible	Can be made, tested, and iterated on within a 3-6 month period
Flexible	The person with LIS can communicate in a variety of ways, depending on their needs
Table 4.1. Initial constraints for filtering	

The initial filtering left us with 19 viable and unique solutions (Figure 4.6)

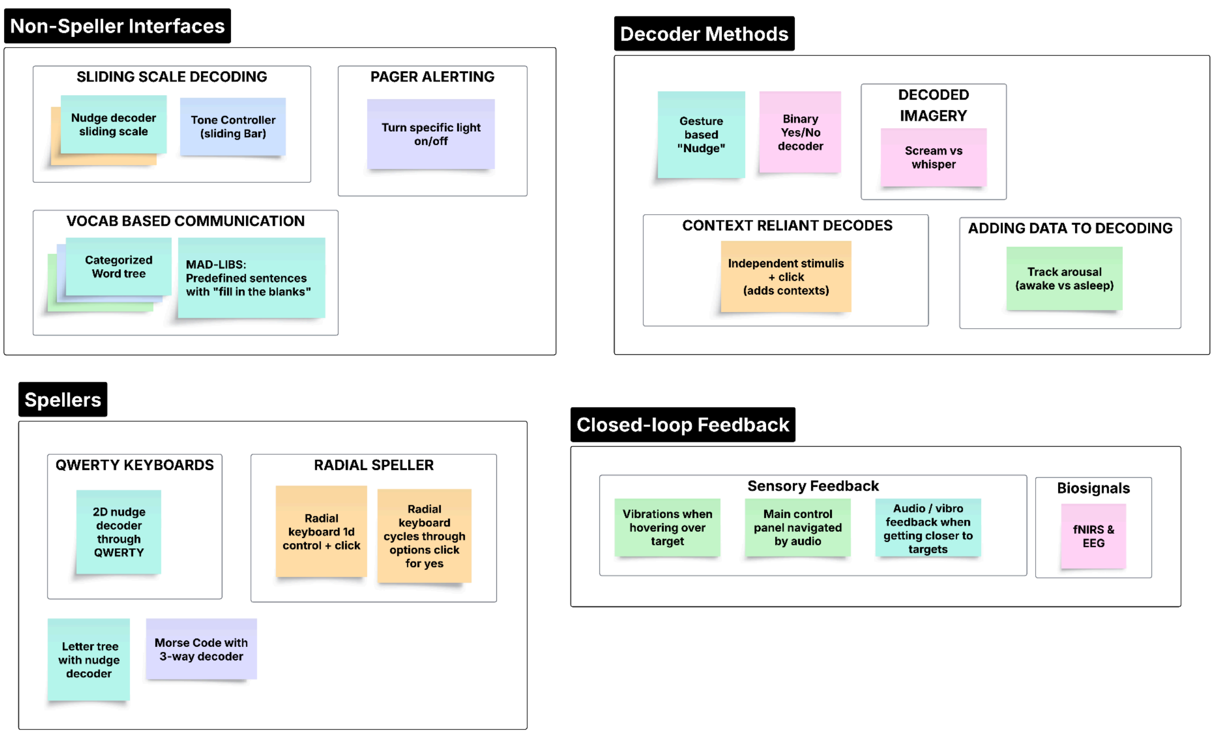


Figure 4.6. Solutions remaining after initial filtering

4.B.ii. Leading Concept Selection

From the viable concepts above, we developed three potential solutions that combined aspects from the various categories (Figure 5.7). These three solutions were an arousal tracker, which would show caregivers and researchers in the room how awake the communicator was via a visual interface. A Morse code communicator where the user would spell out letters using dots and dashes, and finally a Sliding Scale method in which a user could move a cursor along a number of targets on a scale.

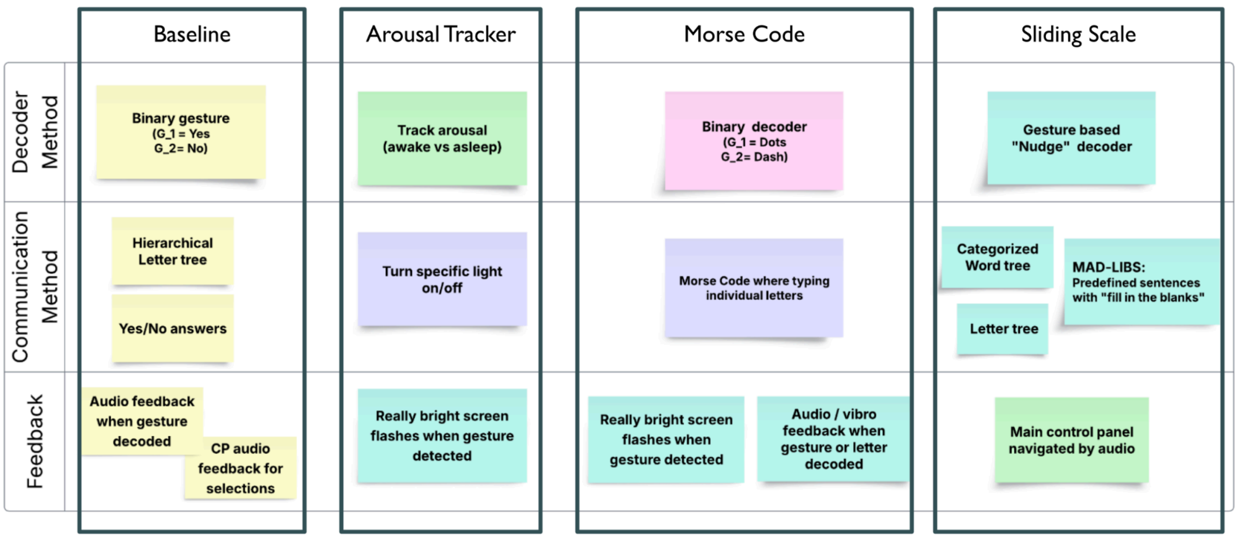


Figure 4.7. Leading concepts

These three concepts were compared against each other in their ability to improve on the baseline via the Pugh ranking method (Yock et al., 2015). The Pugh matrix uses a variety of Pairwise comparison matrices to determine which of the developed solutions best meets the user's needs relative to a set baseline system. The solution that had the best score was then seen as the leading concept and would be explored further.

System Requirement		Baseline	Concepts					
			Initial Results			Weighted Results		
	Weight		Sliding Scale	Morse Code	Arousal	Sliding Scale	Morse Code	Arousal
Stable and consistent decoding	4	0	1	-1	0	4	-4	0

Primarily non-visual cues	2	0	0	0	-1	0	0	-2
Requires minimal cognitive load	3	0	-1	-1	1	-3	-3	3
Can use independently	5	0	1	1	1	5	5	5
Can use for extended periods	1	0	1	1	1	1	1	1
Offers Visual feedback	4	0	1	0	1	4	0	4
Easy to understand	2	0	1	-1	1	2	-2	2
Tracks users prior statements	3	0	1	1	0	3	3	0
Some ability to "control" the conversation	1	0	-1	0	0	-1	0	0
Instills confidence in T17's arousal	5	0	1	-1	1	5	-5	5
Allows for participant consent	6	0	1	1	0	6	6	0
Primarily uses non-visual cues	4	0	1	1	0	4	4	0
Offers visibility of system status	9	0	1	1	1	9	9	9
Uses familiar mapping	3	0	0	1	0	0	3	0
User "exit"	5	0	1	0	-1	5	0	-5
Standardized interface	7	0	1	1	1	7	7	7
Robust system (preventing errors)	8	0	1	0	0	8	0	0
Minimal user memory load	6	0	1	0	1	6	0	6
Flexible use	1	0	1	-1	0	1	-1	0
Minimalist design	2	0	1	1	1	2	2	2
Totals		0	14	4	8	68	25	37

Table 4.2. Results of the Pugh matrix selection process

Within the results of our Pugh matrix, we observe that the "Sliding Scale" concept has the highest weighted and unweighted score. Hence, per the Pugh Matrix selection method, the Sliding Scale interface with audio feedback and a nudge decoder was the solution with the highest probability of improving communication. This result was also supported by the communication recommendations set forth by ALIS, where people with LIS can respond to a multiple-choice question by attempting a number of gestures equal to the choice's location within the options (Gaudeul, 2017).

Répondre en validant par OUI une fois pour la première proposition, deux fois pour la deuxième etc. Par exemple, à la question "veux-tu regarder (TV) la première chaîne, la deuxième, la troisième, Canal +, ou Arte ?", la personne non-parlante répondra en validant quatre fois OUI pour "Canal +".	Respond by pressing YES once for the first option, twice for the second, and so on. For example, to the question "Do you want to watch (TV) Channel 1, Channel 2, Channel 3, Canal+, or Arte?", the non-verbal person will respond by pressing YES four times for "Canal+".
a. Original communication guidelines as originally written in French (Gaudeul, 2017, p. 12)	b. Communication guidelines translated into English by DeepL's Translation AI (DeepL, 2026)
Table 4.3. Communication guidelines for multiple-choice open-ended questions	

4.C. Final Concept Selection

Based on our prior research and the AAC recommendations from the ALIS, and the results of the Pugh matrix, we decided to move forward with the "Sliding Scale interface," which uses audio navigation feedback with a nudge decoder. This system uses a hierarchical setup and allows for communication using a speller and a categorized core vocabulary, and would be highly customizable to the end-user's needs.

Chapter 5: Prototyping

5.A. Initial Iterations

With the sliding-scale determined to be the leading solution, we began developing low-fidelity structural blueprints, known as wireframes, of the interface. Initially, these were made by hand and then shifted over to Miro with version tracking.

5.A.i. Core design elements

In the initial versions of the Sliding Scale, we were required to make several significant decisions, notably regarding the number of responses available on each scale. While developing the choices and selections, we used Neilson's 10 usability principles for user interface design as guidance (Nielsen, 1994). We determined that the optimal number of targets per menu was seven.

Per Nielsen's heuristics, a user should easily be able to undo an action and decide when and how they want to interact with the system. We decided that within each scale, there would be one target that allows the user to either return to the parent menu or take no action. We called this the *null* target. This target would also ensure consistency between each menu, as the end-user would always start their control on the *null* before accessing the other varying target values.

We standardized the number of clickable targets to six per menu. This decision was based on prior categorical models of functional independence and communication that rely on six major categories. Functional independence is most commonly analyzed using the Katz activities of daily living (Edemekong et al., 2026). The tool assesses a person's ability to complete six self-care tasks: bathing, dressing, toileting, transferring, continence, and feeding (Katz, 1983). This method of functional assessment is typically used to establish a common understanding amongst all clinicians involved in patient care. In communication, notably in storytelling, the 5W + H framework is frequently used to observe and understand a story's context and details (A. Holstein et al., 2012). The framework consists of six investigative questions: who, what, where, when, why, and how. This framework can be seen in a variety of fields, including project management, investigative journalism, and decision-making (Martin, 2015; Mazzei, 2023; ProductPlan, 2026). When communicating emotions and feelings, a common tool is a "wheel of emotions." This is a categorical model of emotion by Paul Ekman, which divides human emotions into six primary categories: Anger, Disgust, Fear, Happiness, Sadness, and Surprise (Ekman, 1992). These types of categorical emotion models are frequently used in language research as an annotation tool. Ultimately, these varied models share a common thread: they serve as structured frameworks that enable systematic information gathering and assessment.

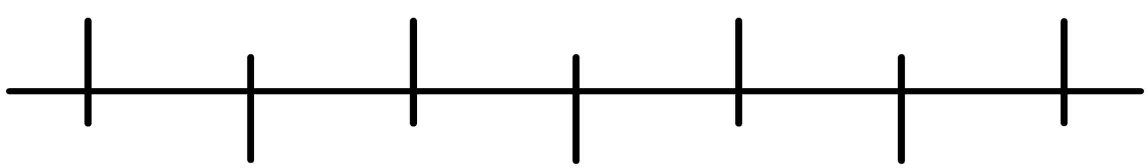


Figure 5.1. Finalized number of targets on each Sliding Scale

5.A.ii. Hierarchical Structures

Once we determined the number of targets on each menu, we focused on expanding the range of communication methods. AACs frequently use a variety of communication styles, including free spelling, yes/no answers, and predetermined core vocabularies (Gaudeul, 2017). This allows people with LIS the freedom to choose how they want to communicate (Lugo et al., 2015). Per the ALIS recommendations, the AAC was divided into categories, each allowing a different method of communication: core vocabulary, yes/no responses, cued sentences, and a free-typing section (Gaudeul, 2017). This variety allows end-users to communicate more quickly, enabling them to use more common words and spell out more complex ones if needed. Within the “Sliding Scale” interface, we created 6 main categories of communication: Core Vocabulary, Quick Responses, Cued Sentences, Numbers, and Alphabet.

Our primary goal for this AAC was to allow the user to quickly communicate needs relating to ADLs.

Core Vocabulary

The core vocabulary, or “categories”, section consists of words that are commonly involved in T17’s communication. This primarily consists of words associated with his care and comfort. Using examples from the ALIS guide, along with other developed AACs. We created the first categories.

The primary goal for this AAC was to allow the user to quickly communicate needs relating to activities of daily living. So initially, the category was titled “needs” and only allowed for the communication of needs related to independent daily living. Using the ADLs as the method of hierarchy. However, when using this system, we frequently observed that this method of organization did not allow the participant to request his methods of entertainment and related requests, like eye care, which commonly included ointment application, putting on or taking off his goggles, glasses, and eye patches, were all in different categories.

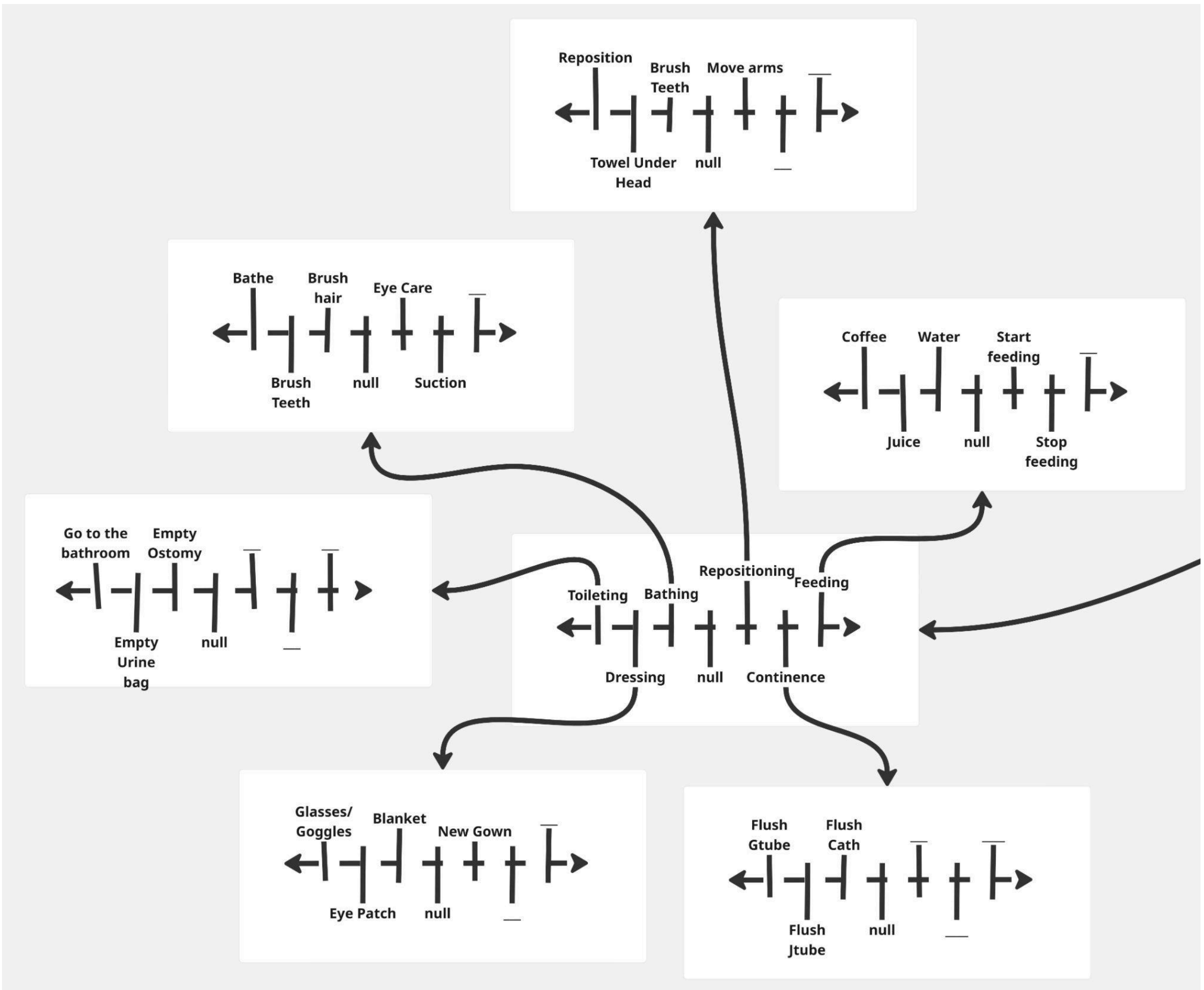


Figure 5.2. Core vocabulary target values: iteration with categorization via ADLs

We then attempted to divide the care themes by the anatomy the words or actions interacted with. For example, if the user wanted eye care, they could navigate to the Head/Neck category to see all care related to their face and eyes. We used the outlines of a medical anatomy textbook to define the division of human anatomy. (Morton et al., 2019).

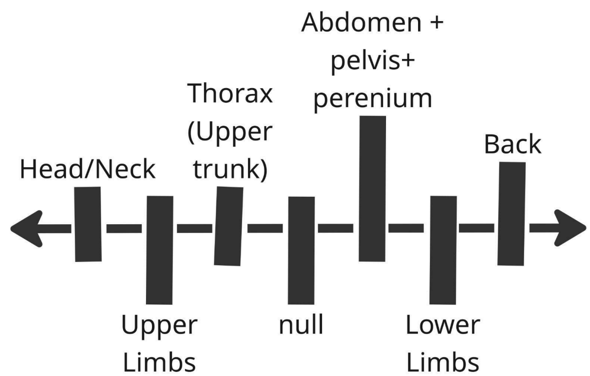


Figure 5.3. Core vocabulary target values: iteration with categorization via anatomy

However, the user's primary vocabulary is not used solely to communicate their anatomical or ADLs. Some of the most commonly used terms included the names of their CPs or clinical staff and words related to comfort and entertainment (e.g., radio, television) (Gaudeul, 2017; Light et al., 2019). To ensure that the hierarchical structure of the word bank allowed the end-user to communicate all of their most commonly used words easily, we created a final categorization of T17's core vocabulary, which blended T17's initial core vocabulary and the Katz classification of ADLs (Figure 5.4).

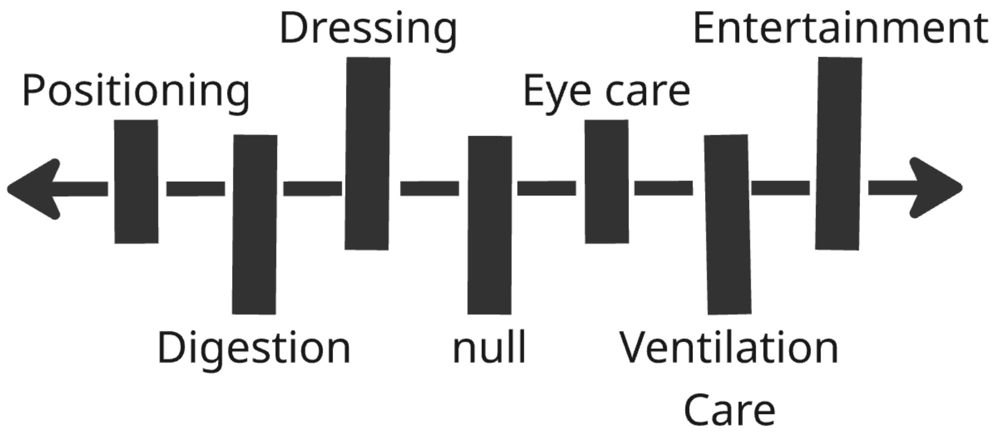


Figure 5.4. Core vocabulary target values: final iteration

Free typing

Free typing communication, also known as keyboards or spellers, allows the end-user to write out each letter of a word, sentence, or phrase. This method of communication can sometimes be more tedious or take longer than other methods, but, in turn, allows the end user to be free from a small vocabulary. Per the Nielsen heuristics, the interface systems should match or replicate systems that the user is familiar with (Nielsen, 1994). We therefore divided the alphabet into the same categories that the participant used for communication. We repeated the same process for the “Numbers” category.

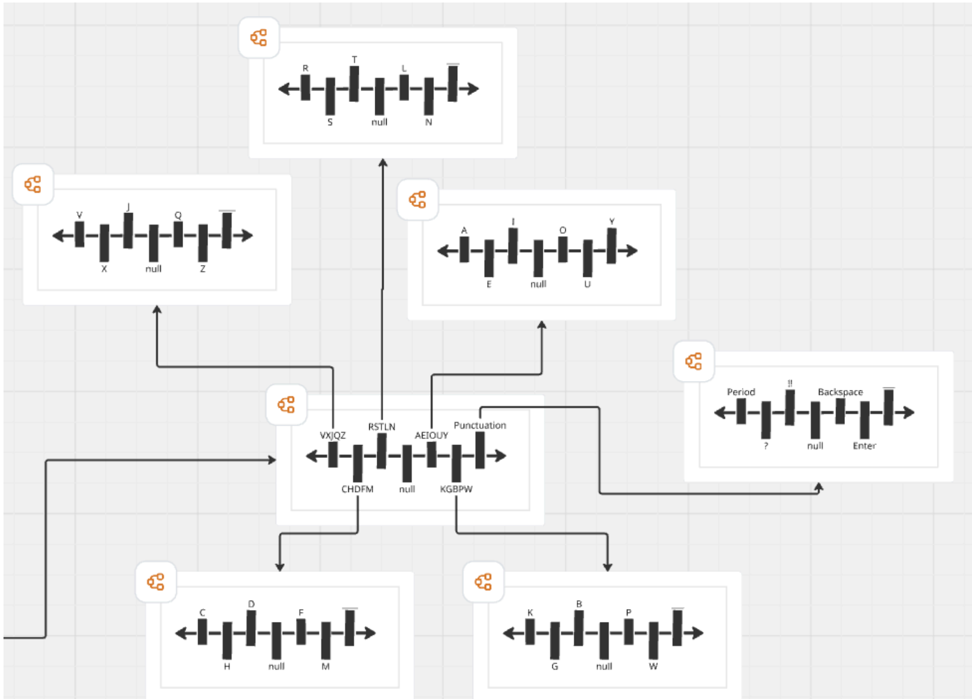


Figure 5.5. Free Typing target values

Within both categories, we added an option labeled “Punctuation”. The punctuation category consisted of actions or punctuation options that allowed the user to add contextual cues to their communication (Figure 5.6). Within the category, we also added backspace, enter, and space actions. These allow the user to delete the previously selected letter, submit their writing, and add a space between words, respectively. These are key components of communication: being able to correct oneself, finalize a statement, and distinguish words within a statement.

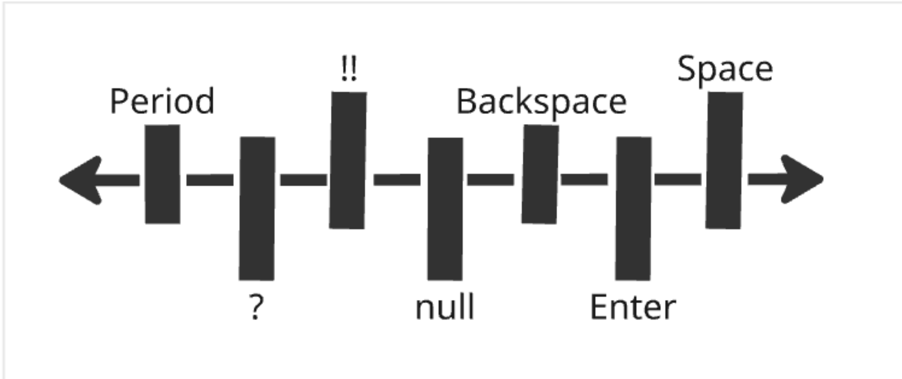


Figure 5.6. Target values within the *Punctuation* category

Quick Responses

The Quick Responses section allows for Likert-type responses to questions. By using Likert scales, the user can answer questions with more degrees of response than a simple yes-or-no response (Figure 5.7). This is important for communication, as it provides more context and more specific information to communicators, which ensures correct buy-in to questions (Gaudeul, 2017). Rather than having the scale go from one extremity to the other, we moved the responses situated where the participant can access the binary answers of yes/no with reduced effort. We did this as these will be frequently used values in T17's daily communication.

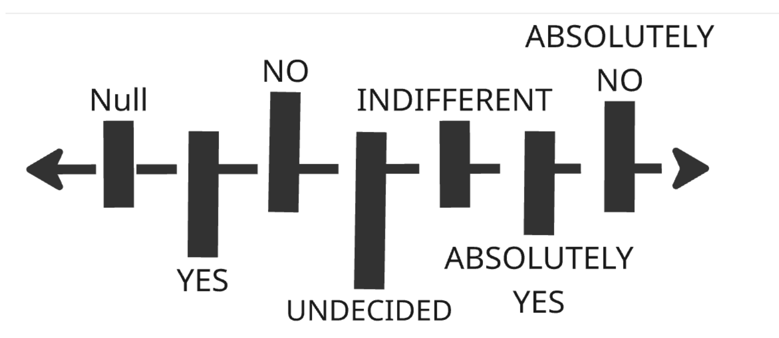


Figure 5.7. Quick Responses target values

5.A.ii.4. Sentence Mode

The system's sentence mode was developed using the concepts of colorful semantics. Colorful semantics is a tool used by Speech-Language Pathologists to teach students about sentence syntax and grammar. It divides words into categories based on their grammatical or semantical importance to facilitate language learning and communication (Vermandel & Puffet, 2021). Each category is associated with a different color that provides additional context for the learner or communicator.

In the sentence mode, the user is prompted to select the values of the syntactic components of a simple sentence: subject, verb, object, and context, in that order. The user will first be prompted to select the sentence's subject within the subject category. The user will be notified of the menu's category with the system orally stating "Subject" and visually with the interface's background turning yellow. Once the subject is selected, the user will be prompted to select the sentence's verb from the predefined verbs available. The process will then repeat for the sentence's object and context. The user will be notified of which syntax component they are currently prompted to select by the system orally stating the Syntax component (e.g., "Subject", "Object"), and visually with the system's background color changing to its respective color as defined by our color-coded method (Table 5.1).

Syntactic Category	**Background Color**	**Contents**
Subject	Yellow	*ME/I - YOU - THEM - CAREPARTNER - CLINICIAN - OTHER*
Verbs	Green	*DO - LIKE - AM - NEED - FEEL - WANT*
Object	Blue	*PERSON - NEED - EMOTION -*
Context	Pink	*TIME - DIRECTION - LOCATION - ANATOMY - NEGATION*

Table 5.1. Overview of the Color Coding Model with their associated syntactic categories used in sentence mode communication

This system would allow the end-user to engage in a more grammatically correct communication method, which could allow for increased understanding from caregivers and researchers, and ultimately better communication outcomes.

5.A.iii. Control Paradigms

While developing the system's interface, we had to simultaneously determine the control paradigm T17 would use to operate it. We developed three main paradigms to test with T17, each with its own advantages and disadvantages. The common thread among these paradigms was the use of a trinary discrete-state decoder that mapped the following actions: Do_Nothing, Gesture_1, and Gesture_2. We used these decoder restraints to determine the various control methods of manipulating the Sliding Scale interface (Figure 5.8)

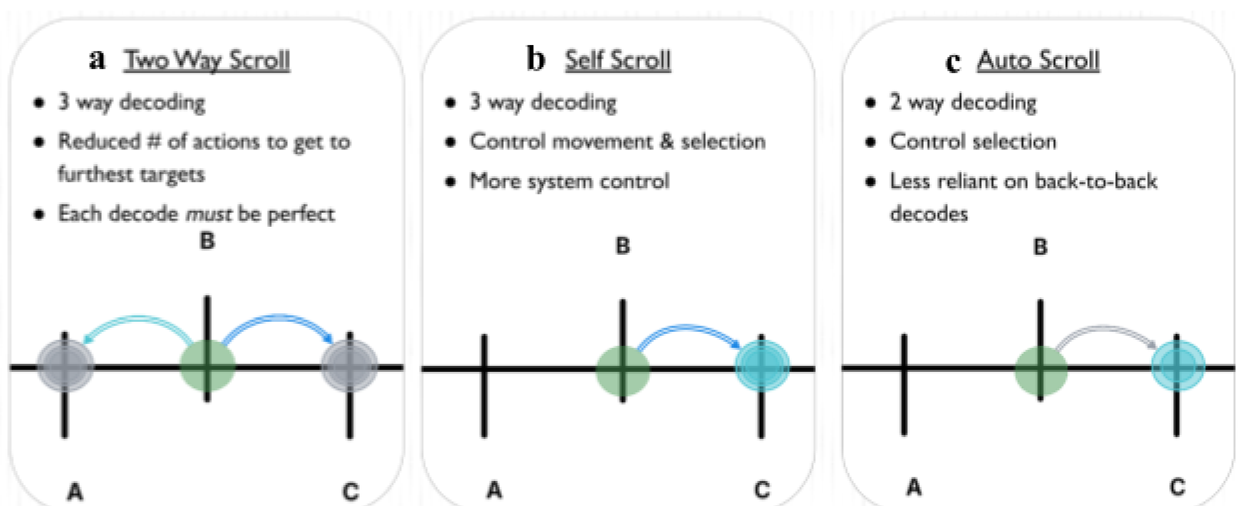


Figure 5.8. Developed control paradigms for manipulating the Sliding Scale: Two-way scroll, Selfscroll, and Autoscroll.

The light green represents the starting point of the cursor, double-lined arrows represent actions completed to move the cursor to a neighboring target, concentric circles represent the number of attempts made to select a specific target.

Two-way Scroll

The initial paradigm allowed the user to move their cursor left and right depending on the gesture performed. In this setup, the user would also select a target by dwelling on their desired target for a certain number of trials (Figure 5.8.A). The advantage of this control mechanism was that, in most trials, it took 6 actions to select a target. If we used this two-way control, we could also ensure that the two answers we thought the person was most likely to reply to would be equidistant and require the same number of gestures to reach. The disadvantage of this method is that the user must perform ternary decoding (DoNothing, Gesture 1, Gesture 2), which can be more complex than binary decoding (DoNothing, Gesture 1).

Selfscroll

The Selfscroll paradigm allowed the user to move their cursor one target to the right by completing two Gesture_2 attempts. The user would then select the target by completing three Gesture_1 attempts (Figure 5.8.b). The advantage of this control mechanism was that the control paradigm did not rely on DoNothing decodes, which were the default output if the decoder was unsure of the attempted gesture. This system allowed the end-user to have direct control of the system's movement and selection activity. The disadvantage of this method is that the system requires trinary decoding (DoNothing, Gesture_1, Gesture_2), which can be more complex than binary decoding (DoNothing, Gesture_1).

Autoscroll

The Autoscroll paradigm mimics a scanning interface where the cursor would move one target to the right each time the NoGesture was decoded. This allowed the participant to only focus on selecting their intended target by completing an initial Gesture_1 and then completing a second Gesture_1 within four attempts to confirm the selection (Figure 5.8.c). The advantage of this control paradigm is that the system relies on binary decoding (DoNothing, Gesture_1) rather than trinary. The disadvantage of this system is that the end-user is more reliant on the system's scanning speed.

5.B. User Testing

A feature of BCI research is the "iterative process of modifying interventions in response to participant feedback" (Klein et al., 2018). We tested a miniaturized version of the "Sliding Scale" interface with the Wizard-of-Oz (WoZ) user testing task, paired with in-depth survey data collection to ensure a rapid iterative process between intervention modification and participant feedback.

The WoZ user testing method was coined by J.F. Kelly in 1980 (Kelley, 2018). This method allows a user to interact with an interface without the backend being fully implemented. In this method, the user only sees the front end, and a researcher or engineer then manipulates the interface to respond to the user's interaction. The researcher acts as the "wizard behind the curtain". This method is commonly used in design engineering and allows researchers and engineers to test the validity and usability of minimum viable products. And iterate through a variety of interface versions, as more user feedback is received.

Communication with people with complex communication needs, notably those with CLIS, can be limited to binary questions. Surveys, including NASA TLX, eQUEST 2.0, among other surveys, were developed and modified to work within the BCI framework (Peters et al., 2016). Unfortunately, these surveys include an open-remarks section, which can be difficult for people with CLIS who use more low-technology AAC methods. However, communication with people with CLIS via yes/no questions can be guided to elicit consistent and honest responses (Fried-Oken, 2000).

5.B.i. Initial User Testing

Aural Instructions

Since the interface relies primarily on aural feedback, it is important to ensure that the end-user's mental model of the interface matches the system's functional model.

To ensure this, we iterated on the Sliding Scales' oral introduction that would be shared with the end-user. We tested the text's ability to get the message across by reading it to various able-bodied people and asking them to draw how they imagine the system working. After multiple iterations of text, the following description was finalized.

> *During this session, we want you to imagine a horizontal row of seven (square?) targets where each target represents a distinct value. On this row, we want you to imagine a cursor that you are attempting to control. To navigate to the other targets, move the cursor to the right by attempting [**specific gesture x number of times**] in a row and when you want to select the target you're on, attempt [**specific gesture x number of times**] in a row.*

These oral instructions were used to ensure that the end-user had a correct mental map of the system.

Methods for data collection

We used the WoZ methods to test multiple interfaces and imagery with participants while reducing development time, so we could spend the most time ensuring the interface worked best for people in situations similar to T17's.

In addition to using the WoZ method, we introduced T17 to the Sliding Scale interface by creating a smaller scale version of the interface to test with T17 (Figure 5.9).

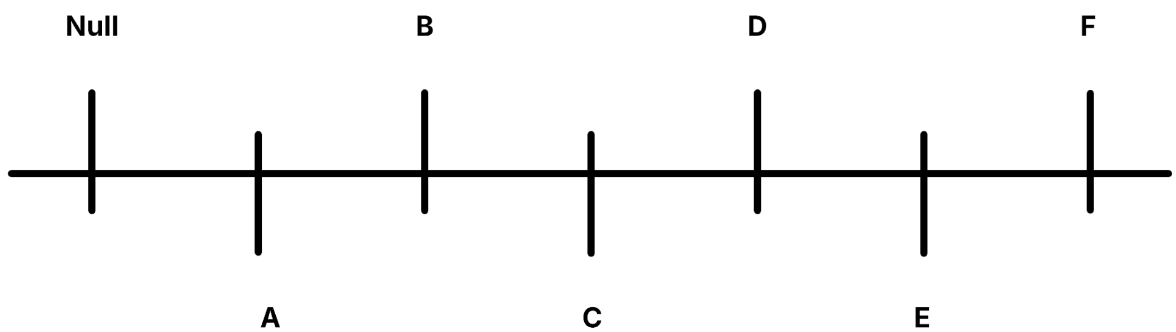


Figure 5.9. Visual representation of the reduced Sliding Scale Aural interface

Before each block, the participant was reminded of the control paradigm they would be using and the mental map of the Sliding Scale interface. During the block, T17 was asked to use the interface and the established control paradigm to answer basic questions regarding the alphabet (Table 5.2).

Prompt #	Researcher spoken prompt:	Expected Answer
P1	What is the letter before B as in "bat"	A
P2	What is the letter after D as in "dog:	E
P3	What is the letter before C as in "cat"	B
P4	What is the letter after E as in "eagle"	F
P5	What is the letter before D as in "dog:	C
P6	What is the letter before E as in "Eagle"	D

Table 5.2. Table of prompts used during Wizard-of-Oz testing

After each block, the participant was asked to answer the usability surveys with the help of the researcher or carepartner.

Results of data collection

We ran the WoZ sessions with the reduced Sliding Scale with participant T17 on trial days 729, 739, and 746.

The WoZ task is a great method to test varieties of the same interface with minor changes within it. After completing the tasks, we were able to determine the number of successful attempts it took for the user to complete an action (Table 5.3).

	Action Map		
Control Paradigm	**Move Left**	**Move Right**	**Select Target**
Twoway scroll	Gesture_1(x2)	Gesture_2 (x2)	Do_Nothing (x6)
Selfscroll		Gesture_2 (x2)	Gesture_1(x3)
Autoscroll		Do_Nothing (x2)	Gesture_1 (x2)

Table 5.3. Final action map for the three control paradigms

Once the action maps were solidified, we asked the research participant to complete a comparison survey where T17 was able to share his preference of control paradigms in specific scenarios (Table 5.4).

Trial Day	**739**	**746**
Which device allows you to communicate more efficiently?	AS	AS
Which device allows you to communicate more accurately (fewer errors in the selection process)?	AS	AS
Which device enables you to communicate the most independently?	AS	AS
Which device is the most practical to use on an everyday basis?	CM	NP

Table 5.4. T17 comparison survey responses on trial days 739 & 746.
CM = current method, TW= two way scroll, SS = selfscroll, AS = autoscroll, NP = no preference.

We observe a continuous and strong preference for the autoscroll method throughout the survey results for the four primary questions, leading us to conclude that the Sliding Scale system worked best with the autoscroll paradigm for T17.

5.B.ii. Secondary User Testing

Methods

Once we confirmed the correct control paradigm, we allowed T17 to attempt to spell with an evolved version of the Sliding Scale in which T17's hierarchical alphabet method was present (Figure 5.10)

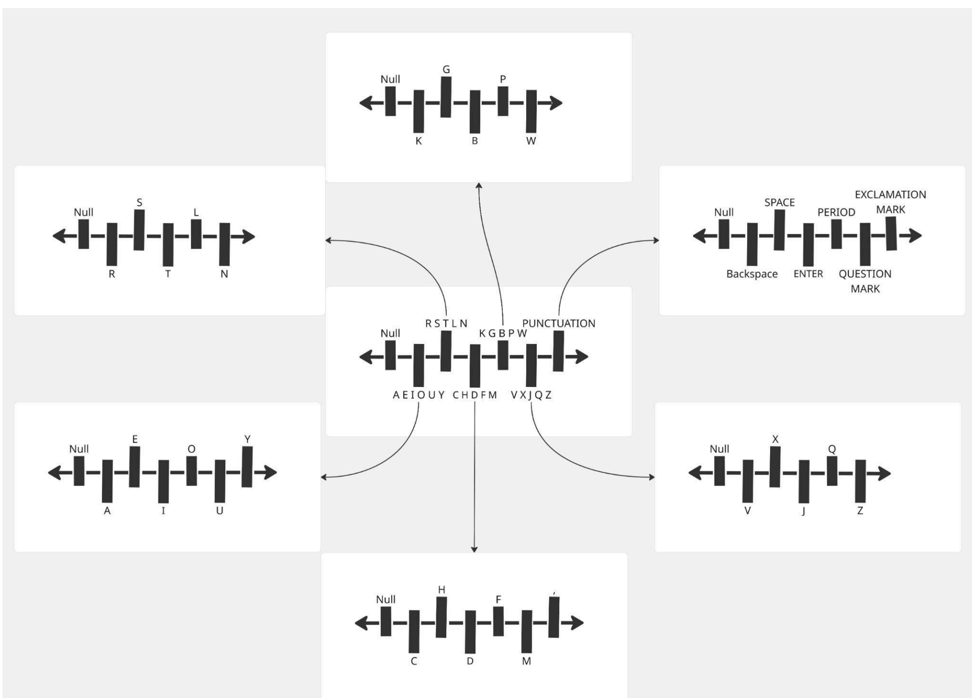


Figure 5.10. Hierarchical structure of alphabet within the Sliding Scale interface

The primary goal of this user testing cycle was to determine if the buttons were in the correct locations and to determine if the autoscroll method continued to be favored by the participant. To confirm the participant was able to communicate efficiently, we asked the participant to attempt spelling the word *KEYBOARD* as researchers did when testing the radial keyboard (Bacher et al., 2015).

This was then followed by T17 using the system to communicate with their carepartner. Finally, T17 was asked to answer the same surveys as during the initial round of user testing.

Results

We ran WoZ sessions with the hierarchical alphabet speller integrated into the Sliding Scale with T17 on trial days 746, 748, 753 & 755. However, we were unable to collect interface blocks on trial days 748 and 753 due to poor decoder accuracy and participant fatigue levels.

Trial day 746

During the free communication portion of the session, T17 used the Sliding Scale with self-scroll to spell **"***CHECK APPT***"**. The CP knew exactly what the T17 meant by this and checked his email to see if he had received any updates regarding future clinical appointments. T17's request to monitor his schedule and email is consistent with attempting to complete an instrumental ADL (Edemekong et al., 2026).

Similarly, T17 was asked to share their favorite color with the team. T17 was able to use the system to communicate **"***DARK RED***"**. The fact that t17 was able to not only define his favorite color but the hue of said color shows the extent of communication ability that is available when using the Sliding Scale system.

Trial day 755

On trial day 755, we prompted t17 to spell the word “KEYBOARD” using the speller interface. T17 had spelled “*KEBAI*” and was attempting to delete the incorrectly selected letters “*A*” and “*I*”. While attempting to select the *Punctuation* target, T17 was repeatedly accidentally selecting the targets before *Punctuation*. He would then select the Null target among the incorrectly selected targets, and he would be returned to the Null target on the Main page. T17 would then repeat the process of attempting not to confirm his erroneous group selections. After observing this dance repeatedly, we paused the task and asked t17 for feedback on the placement of the Punctuation target. T17 shared that he did NOT like the current location at the end of the scale, and we confirmed that he wanted to try the interface in which punctuation was the first target on the scale. We then continued the copy task, and T17 was able to delete the incorrect selections and spell “*KEYBOARD*”.

On trial day 755, we attempted an independent communication task with T17. Since there were no implemented *Yes* and *No* targets, the research team designated that selecting the *null* target on the main menu twice would be considered a “*Yes*”. T17 also requested that, while he was typing, the communicators in the room guessed what he was attempting to communicate with yes/no questions. T17 began the independent communication task by spelling the letters “*COF*”. T17’s CP asked the participant if he was asking for coffee. To which T17 replied yes. The CP then fetched clinicians in the room to confirm T17’s request and serve coffee.

5.C. Final Interface

The final interface (Figure 5.11) gave both aural and visual feedback to all stakeholders within the room.

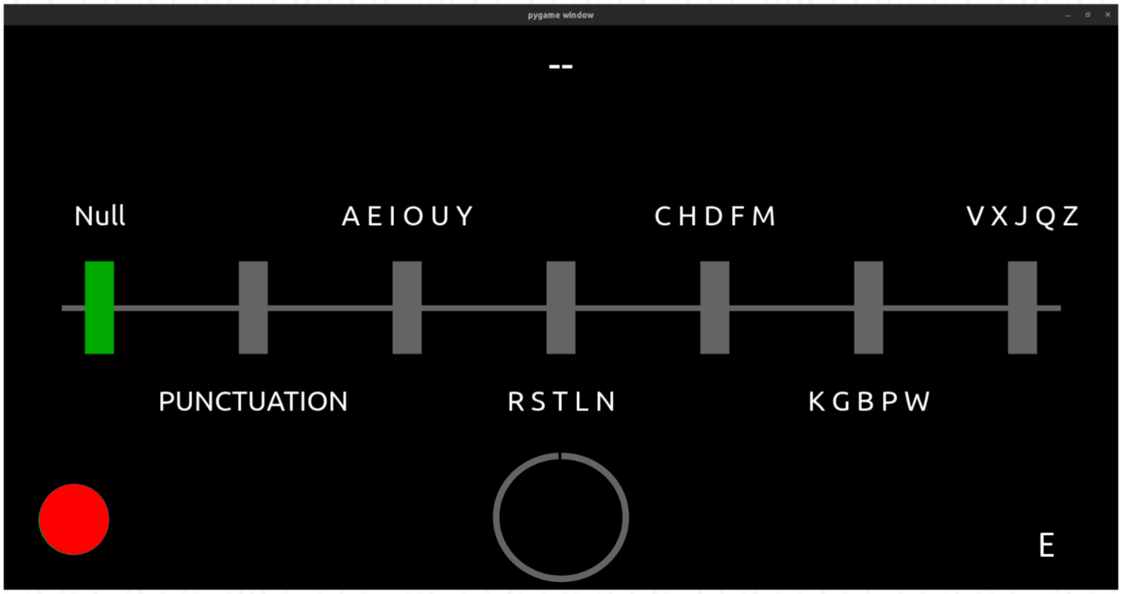


Figure 5.11. The top-level typing selection slider

In the lower left corner, there is a red circle that notifies the end-user of the trial status. The circle turns green with the trial's go-cue and red during the trial's preparatory period. These visual cues are accompanied by audible tone feedback that tells the participant when it's time to attempt the gesture versus when not to attempt it.

The two dashes in the middle are where the decoded gestures appear; this will change to the decoded gesture (Gesture_1, Gesture_2, or Do_Nothing) depending on the gesture decoded. The green line on the null axis in the cursor moves throughout the interface as the user moves around it. Whenever it jumps onto a new target, the target's value or name is said aloud.
In the lower-right corner of the interface, the most recently selected item is observed. This reduces the memory load on the caregiver, as they do not always have to remember every output of the communicator. In future iterations, we want all selected items to remain in this area until the *Enter* target has been selected. In the lower middle portion of the screen is a progress tracker. This acts as a visual cue to show how many targets or additional attempts the participant has to

complete in order to complete a set gesture. When a user completes an action, a portion of the circle turns green. For example, in the case of autoscroll, if the end-user completes one Gesture_1, then half the circle will turn green. The entire circle will turn green once the second Gesture_1 is decoded.

In future iterations, we want to improve the audio feedback given by the system to rely less on the robotic voice and define some chimes and tones that signify the different gestures decoded and determine additional audio feedback for the progression bar.

Chapter 6: Discussion & Conclusion

6.A. Discussion

By observing T17 and his CP's use of the system, we found that the system met the stakeholder and design needs defined at the beginning of the Biodesign methodology.

System Flexibility and Efficiency:

When T17 missed his desired target, he would select the following target. Once in the sub-hierarchy of the target, he would select the target's null target to return the cursor back to the null target on the parent menu. He would then wait for the cursor to reach the target again and reattempt to select it. These innovative methods of interacting with the interface demonstrate the interface's flexibility in system use, which is a critical requirement for good user interfaces.

Despite the final version of the interface not containing a "yes"/no answer option, the CP and T17 found new ways to answer yes/no questions. For each yes/no question, the CP defines a yes value and a no value for targets within the menu. For example, if T17 is in the Vowel menu, the CP may define target "*E*" as yes and target "*Y*" as no. This method of yes/no communication allows the CP to steer the conversation (asking for a yes/no answer) while giving T17 the ability to decide whether he wants to answer the question.

These innovative methods of interacting with the interface demonstrate the interface's ability to facilitate communication.

Independent Communication

The communication interface has also allowed the CP and T17 to have more independence. The CP can focus their energy and efforts on supporting ADLs, rather than spending the cognitive load tracking T17 answers. This even allows the CP to leave the room (if required), and the participant can still communicate independently.

Indicating Arousal Levels

Similarly, by standardizing and increasing the number of gestures required to select a letter, the CP and clinical staff can potentially feel more confident in T17's arousal levels. If the participant is selecting letters that don't go together, the CP and other stakeholders may be more likely to believe that T17 is asleep.

Communication of wants

On trial day 755, T17 was able to request a coffee from his CP using the communication interface. This is not something T17 is normally able to request on his own, and rather has to be asked if he wants coffee by his CP. The system managed to aid in the communication of needs, such as ADLs, while also expanding his ability to communicate wants, such as specific drinks.

Ultimately, this system has been shown to add value and improve T17's communication methods and abilities. Through increased flexibility, independence, and innovative approaches to interaction, T17 and his CP have leveraged the interface not only to meet daily needs but also to enhance quality of life. The system's adaptability highlights its potential for broader impact, empowering users with complex communication needs to express themselves more fully and autonomously.

6.B. Conclusion

T17, our clinical trial participant, presents with CLIS and uses his intracortical BCI to communicate his needs. Unfortunately, he has experienced signal degradation of recorded neural signals over time, rendering high-performance BCIs and three-way discrete decoders less effective. To address this, we used the Stanford Biodesign method to ideate 91 unique solutions, which, using various filtering methods, led to defining our leading concept. Our user testing confirmed that the sliding-scale interface paired with autoscroll best balanced system needs and decoding accuracy with user requirements such as independent communication.

The Sliding Scale with autoscroll system has already shown promising impacts on user independence and CP dynamics. For T17, the system allows him to have a more proactive role in his care. For his CP, the system has reduced the cognitive and memory load required by the prior system, including the need to track complex letter hierarchies. Additionally, the stakeholders have developed innovative methods of using the interface to meet more specific communication needs, such as answering specific yes/no questions during complex communication. Ultimately, stakeholders can still receive the information they need while maintaining T17's ability to decide whether to engage.

Our research also addressed significant challenges inherent in qualitative research involving people with CLIS. To facilitate user-centered design, we employed Wizard-of-Oz testing, which allowed rapid iteration of interface imagery and control paradigms before the backend was fully implemented. While gathering usability feedback via yes/no questions introduces the potential for response bias, we took several steps to ensure the validity of T17's input, including repeating responses to confirm and restating questions when errors were detected.

Looking forward, several future directions could further enhance the system's utility. Building on our current findings, implementing the *Predefined Vocabulary* and *Sentence Mode* wireframes will support more rapid, grammatically complex communication than single-word requests. Additionally, improving the current robotic aural feedback by introducing distinct chimes and tones to represent different system states or progress milestones will further reduce the user's memory load. These adjustments aim to create a more intuitive, robust, and gaze-independent communication interface that is minimally reliant on voluntary movements and neural signal acuity.

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