Use cases of tablet-based BCI-AAC in individuals with physical and speech impairment

Experimental Protocol

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1 Context

Individuals with severe physical impairment and impaired communication abilities often require assistive and augmented communication (AAC) devices to efficiently engage with their caregivers, social network, environment and technology in an autonomous way. Current solutions are often based on gaze tracking, but this approach is not always feasible, due to the condition or impairment of the user or due to practical reasons. This can include eye motor impairment, difficulty positioning the eye tracker, medical interventions that occlude the eyes such as CPAP or ventilation masks or visual corrections Furthermore, solutions based on eye tracking alone can be unstable and are not always robust, and they are often experienced as uncomfortable if they rely only on dwell time or eye blinking to make selections.

Alternatively, selections in such an AAC interface can be made using another control signal than eye gaze, such as those that can be measured with electroencephalography (EEG) or electromyography (EMG). Taking this approach further, eye tracking can be fully replaced if sufficient degrees of freedom for control can be achieved using a suitable control signal

The aim of this study is to validate highly technological AAC solutions leveraging a brain-computer interface (BCI) based on EEG sensors in their ability to have a short term impact on the quality of life of individuals with severe physical and speech impairment. Secondly, we aim to gain and expanded insight in the realistic and practical hurdles in BCI-AAC technology development.

To ensure that the conclusions of this study and further steps taken as a result are impactful and well-positioned in the situation of these individuals, we start from the principles laid out by the user-centered design (UCD) framework [4] presented in table 1.

Principles	**Stages**
P1: understand the user, the task and the environmental requirements	**S1:** understand and specify the context of use
P2: encourage early and active involvement of the user	**S2:** specify the user requirements
P3: be driven and refined by user-centered evaluation	**S3:** produce design solutions to meet user requirements
P4: include iteration of design solutions	**S4:** evaluate the designs against requirements
P5: address the whole user experience	
P6: encourage multi-disciplinary design	

Table 1: The user-centered design (UCD) framework.

In line with **P1**, **P2**, **P3** and **P5**, we start from a system that is already

candidate for at-home, EEG-BCI AAC technology, developed with prior user feedback on efficiency and desirability. We anchor the evaluations performed in the experiments in this study to the MindSpeaker MindClick system (Mindspeaker BCI, Belgium)[1]. Furthermore, all evaluations will be performed in an on-line matter, where biosignals are immediately decoded to provide direct selection feedback, as is the case in real-world operation. This approach constrains us to work within the space of applicable AAC solutions, and the practical, economic and technological reality imposed by using such a devices. In turn, this will lead to valuable insights in translating BCI-AAC solutions from the research lab to the market and the user at home.

Following the UCD stages, we first specify the context of the studied solution (**S1**): we aim to research how such a device can be further developed to an efficient, marketable and automated communication AAC technology for daily home use on the one hand, and on the other hand extend it to a wider public of users that currently do not fit the profile of the device. This is supported by our experience in interacting with severely impaired patients in previous case studies or from testimonials and interview.

As **S2**, we have identified a gap between the current AAC technology offer and the requirements of the target user population of interest, which is the reliance on eye tracking. In order to accommodate patients with severe eye motor impairment or other conditions prohibiting effective eye tracker control, **S3** involved extending the MindClick system with a solution that does not rely on eye tracking. We considered several BCI paradigms and solutions using EMG to make this possible, with as main challenge acquiring control with sufficient degrees of freedom to navigate through the AAC button interface. Ultimately, we opted for a minimal alteration using a *scanning* interface, where selections can be made by clicking through the EEG-based MindClick system.

The protocol below evaluates the developed solution and future iterations, mostly focusing on the **S4**. This protocol can later be reused to evaluate new iterations or features of the device or establish baseline values in specific target user populations and to steer further development. Note that the details, content or structure of the experimental procedure might need to be adapted to the participant in question, due to the heterogeneity of the population of interest.

2 Recruitment

2.1 Inclusion and exclusion criteria

We partially base the recruitment criteria on the BCI user classification system presented by Wolpaw et al. [7]. They present a three-class system:

1. complete locked-in syndrome (LiS) without voluntary movements (including eye movements),

[1] `https://www.mindspeakerbci.com/hardware`

2. the ability to control a single-button switch using very limited voluntary movement, consisting of eye movements or small limb movements, and

3. reduced but substantial voluntary movements (either speech or limb control), able to operate a range of classical AAC devices.

Participants will be **included** if they

1. are at least 18 years old and no older than 60 years,

2. have dysarthria or anarthria,

3. belong to class 2 or 3 according to the BCI user selection criteria presented by Wolpaw et al. [7],

4. have given their informed consent prior to participation.

5. have a (professional) caregiver willing and present to support device usage.

Participants will be **excluded** if they:

1. have a diagnosis of a major medical condition, including any major neurological or psychiatric disorder other than those of interest based on inclusion criterion 3

2. have a predisposition to or a history of any kind of epileptic seizures, including photosensitive epilepsy,

3. have a severe loss in vision or hearing that would significantly impair participation in the experiment,

4. are currently using specific psychoactive medications or substances that could affect the outcome. (neuroleptics or benzodiazepines)

5. are unable to understand the experiment instructions or to cooperate,

We are especially interested in participants that have limitations to the extent or comfort of their eye motor control (partial or full gaze paralysis, uncontrolled gaze movements, or conditions affecting the capability to direct the gaze or fixate), but do not limit recruitment to this criterion. Note that we also do not a priori exclude participants whose condition is currently not fully compatible with the device (e.g., severe spasticity, uncorrected visual impairment, ...), as we are interested in identifying gaps between the current solution and the specific requirements of potential users.

2.2 Case descriptions

The situation of each included participant will be summarized in a case profile to contextualize their experiment outcome. The following data will be collected from each participant to support these case description:

1. Age
2. Handedness (and impact of condition on handedness)
3. Sex
4. Neurological diagnosis and time since diagnosis and symptom onset, from the medical history as assessed by a clinician if possible, otherwise self reported.
5. Qualitative description of visual and oculomotor function according to the visual skill framework Fried-Oken et al. [2], if possible complemented by ophthalmological diagnosis from medical history or as assessed by a clinician.
6. NSUCO eye motor test score [6].
7. logMAR visual acuity score [1].
8. The 'person' form of the ATD-PA survey [5].

If medical evauation is not possible if there is no active involvement of a clinician, or if medical and personal data cannot be requested or stored due to compliance or privacy reasons, the case profile can be limited to the 'person' section of the ATD-PA survey.

3 Experimental design

A structured experiment is set up to assess the contribution of the scanning interface to the MindClick system in specific, and to assess the value, impact and shortcomings MindClick communication system as a whole. In this experiment, participants with severe physical impairment will interact under observation with the system in 3 sessions:

1. Onboarding and supervised session, including a first impression evaluation.
2. Free usage at home or in the patient center.
3. Supervised re-test session, including an overall impression evaluation.

In case participation time is limited or for other practical reasons, the experiment can be limited to session 1. An entry and exit survey polling the participant's expectations and satisfaction are conducted respectively before and after the experiment. Only introduce the device after the entry survey has been completed.

The experiment will require caregiver training and involvement. Non-time-critical questionnaires will be completed at home or in the patient center through the REDCap platform, optionally with the support of a caregiver.

3.1 Supervised Sessions

In the supervised sessions 1 and 3, the participant will be instructed to operate the system according to the following three operation modalities (if able to do so):

1. touch
2. eye tracking + EEG-click
3. scanning + EEG-click

Currently, the MindClick systems offers two main communication modes: a configurable icons interface and a typing interface with text completion. Both will be evaluated.

Each supervised session will evaluate the system along the UCD dimensions listed in table 2 for every modality. Each dimension is assessed by metrics recorded while the participant uses the system to perform controlled tasks. These tasks include copy spelling tasks and using the system to convey an instructed message to a caregiver.

UCD dimension	**Instrument**
Effectiveness	Copy spelling accuracy/error rate Icon copy accuracy/error rate Time and accuracy to communicate concepts to caregiver with AI assistance (spelling interface) Time and accuracy to communicate concepts to caregiver with AI assistance (icon interface)
Efficiency	Copy spelling information transfer rate Workload, through automated NASA task-load index [3]
Satisfaction	Per-modality satisfaction visual-analog scale Overall satisfaction visual-analog scale
Signal quality	Signal-to-noise ratio during MindClick activation

Table 2: Metrics recorded per session as response variables of the experiment.

3.2 At-home use

After completing session 1, the participant can freely use the device over a period of days or weeks at home, in the care home or in the patient center. They can use the interaction modalities and interfaces described above as they prefer. They are allowed to alter the system's settings (in cooperation with their caregiver) to accommodate their needs, ensure proper functionality and to maximally take advantage of the capabilities of the MindSpeaker system.

3.3 Overall impression

After completing all experiment sessions, supervised session 1, at-home use and supervised session 2, the participant's overall experience with the system will be evaluated in an exit survey with the metrics listed in table 3. Note that the resulting questionnaire might seem rather extensive to fill out, especially for impaired participants, but we did not experience issues in the past. If so, sections can be excluded.

UCD dimension	**Instrument**
Satisfaction	Satisfaction visual-analog scale
	QUEST 2.0: reliability, speed, learnability, aesthetic design
	Question for use in daily life
	Subjective interview with user and caregiver about use cases, methods, and feedback
	'Device'-form of the ATD-PA survey

Table 3: Metrics recorded to summarize the full experience of at-home use.

4 Experimental procedure

The experimenter is notified by the recruiting partner of new participant candidates. Consent, eligibility and demographic information survey and the entry survey can be conducted at home or in the patient center, potentially with the help of a caregiver. There is no strict need for the experimenter to be present. For the supervised sessions, the experimenter will make two visits to the participant. These visits also serve to provide and collect the device for at-home use. In Visit 1, the experimenter sets up and explains the device and the first supervised session is conducted. In Visit 2, the second supervised session is conducted. Ideally, Visit 1 and Visit 2 should be one week apart, subject to practical constraints.

4.1 Recruiting and entry survey

1. Recruiting partner informs researcher of potential candidate after presenting
2. Assign participant ID number.
3. Recruiting partner provides description of experiment and informed consent information to user.
4. Verify consent inclusion and exclusion criteria by having the recruiting partner fill out *FORM 1: Consent and eligibility.*

Form	New participant	Visit 1	Visit 2	End of study
1: Consent and eligibility	✓			
2: Demographics and clinical information	✓			
3: Entry survey	✓			
4: Performance evaluation		✓	✓	
5: Satisfaction and workload		✓	✓	
6: Exit survey				✓
7: End of trial				✓

Table 4: Study events and corresponding instruments.

5. **IF** informed consent is obtained **AND** the participant meets all of the inclusion criteria **AND** none of the exclusion criteria **THEN**:

   (a) Provide clinician, therapist or caregiver with *FORM 2: Demographics and clinical information*.

   (b) Have *FORM 3: Entry survey* filled out by the clinician, paramedical assistant, caregiver who does daily follow-up of the participant, or the participant themselve if able.

   ELSE:

   (a) Fill out *Screening failure* section of *FORM 1: Consent and eligibility*

4.2 Visit 1

1. Before participant arrival, verify stable network connection and all functionalities of the device.

2. Position the participant comfortably in front of the tablet, using a monitor support if necessary.

3. **IF** the participant can operate the tablet using touch **THEN:**

   (a) Fill out section *Touch modality* of *FORM 4: Performance evaluation*

   (b) Open the keyboard pane.

   (c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using touch control.

   (d) Open the icons pane.

   (e) Perform the icon copy experiment given by procedure 4.2.2 using touch control.

4. Perform the MindClick onboarding procedure 4.2.3 as below. Make sure this is witnessed by the caregiver who will assist the participant in setting up the device during the at-home use session. Adjust eye tracking and EEG signal calibration during the rest of the session when necessary.

5. **IF** the participant can operate the tablet using eye tracking and MindClick **THEN:**
   (a) Fill out section *Eye tracking + MindClick* of *FORM 4: Performance evaluation*
   (b) Open the keyboard pane.
   (c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using eye tracking and MindClick control.
   (d) Open the icons pane.
   (e) Perform the icon copy experiment given by procedure 4.2.2 using eye tracking and MindClick control.
6. Enable the scanning functionality
7. **IF** the participant can operate the tablet using scanning and MindClick **THEN:**
   (a) Fill out section *Scanning + MindClick* of *FORM 4: Performance evaluation*
   (b) Open the keyboard pane.
   (c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using scanning and MindClick control.
   (d) Open the icons pane.
   (e) Perform the icon copy experiment given by procedure 4.2.2 using scanning and MindClick control.
8. Have the participant fill out *FORM 5: Satisfaction and workload* on their own, with paramedical assistant or caregiver, or with assistance of the experimenter, in that order of preference.
9. Carefully instruct the caregiver and participant how to power the device on and off, set up the EEG headset and eye tracker, and adapt and reset the settings.
10. Verify their capability by having them perform the device setup.
11. Hand over the tablet, charger and monitor arm if necessary, agree on a time frame for the at-home session and leave your contact information to troubleshoot technical problems.

4.2.1 Copy spell experiment

The following sentence cues should be spelled by the participant, in random order:

- Pouvez-vous m'aider à ajuster mon oreiller, s'il vous plaît ?

- Aidez-moi à repositionner mon bras, il est raide.
- J'aimerais savoir quand quelqu'un viendra m'aider à bouger.
- Pouvez-vous me dire quel jour nous sommes aujourd'hui ?
- Je veux changer de position, cette posture est fatigante.
- J'aimerais aller dehors quand il fera un peu meilleur.
- Rappelez-moi l'heure de mon prochain rendez-vous médical.
- Je voudrais choisir mes vêtements pour demain, s'il vous plaît.
- Pouvez-vous régler la hauteur de mon lit, s'il vous plaît ?
- Je souhaite savoir quelles activités sont prévues cet après-midi

FOR EACH sentence cue:

1. Show the cue to the user and make sure they understand the message
2. Give an oral instruction to start the typing
3. Record the time from the oral instruction to the use of the 'Speak' function by the participant.
4. Record the actual spelled sentence and the AI interpretation of the spelled sentence.

4.2.2 Icon copy experiment

The following cued messages should be conveyed through the icons interface in randomized order:

- Bonjour comment allez-vous?
- Obtenez le médecin.
- Obtenez l'infirmière.
- Je ne veux pas manger de pomme.
- J'ai trop froid.
- Je suis triste
- Pouvez-vous allumer la lumière?
- J'ai des démangeaisons!
- Je veux une couverture
- Je veux m'allonger.

FOR EACH icon cue:

1. Show the cue in text form to the user and make sure they understand the message.
2. Give an oral instruction to start icon selection.
3. Record the time between the oral instruction and the selection of the correct icon by the participant.
4. Let the participant search independently for the correct icon through the interface. Record the number of erroneous selections of icons that are associated with a message (i.e. excluding navigation icons).
5. Record the actual spelled sentence and the AI interpretation of the spelled sentence.

4.2.3 MindClick onboarding procedure

1. Position EEG headset correctly and comfortably on the participant.
2. Explain the interface, functionalities and different panes.
3. Attempt to type some words in the spelling interface without prior calibration.
4. **IF** spelling is uncomfortable or inaccurate **THEN:**
   (a) Re-calibrate the eye tracker
   (b) Re-calibrate the EEG signal.
   (c) Re-adjust the MindClick parameters taking into account false positives and false negatives.
5. Give the explicit instruction "Try to adapt your strategy to learn how to use the device."

4.3 At-home use

Make sure to be reachable for technical troubleshooting during this phase. The perticipant is free to choose and switch the operating mode and functionalities of the device.

4.4 Visit 2

1. Verify stable network connection and all functionalities of the device.
2. Position the participant comfortably in front of the tablet, using a monitor support if necessary.
3. **IF** the participant can operate the tablet using touch **THEN:**

(a) Fill out section *Touch modality* of *FORM 4: Performance evaluation*

(b) Open the keyboard pane.

(c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using touch control.

(d) Open the icons pane.

(e) Perform the icon copy experiment given by procedure 4.2.2 using touch control.

4. **IF** the participant can operate the tablet using eye tracking and MindClick **THEN:**

   (a) Fill out section *Eye tracking + MindClick* of *FORM 4: Performance evaluation*

   (b) Open the keyboard pane.

   (c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using eye tracking and MindClick control.

   (d) Open the icons pane.

   (e) Perform the icon copy experiment given by procedure 4.2.2 using eye tracking and MindClick control.

5. Enable the scanning functionality

6. **IF** the participant can operate the tablet using scanning and MindClick **THEN:**

   (a) Fill out section *Scanning + MindClick* of *FORM 4: Performance evaluation*

   (b) Open the keyboard pane.

   (c) Perform the keyboard copy spell experiment given by procedure 4.2.1 using scanning and MindClick control.

   (d) Open the icons pane.

   (e) Perform the icon copy experiment given by procedure 4.2.2 using scanning and MindClick control.

7. Have the participant fill out *FORM 5: Satisfaction and workload* on their own, with paramedical assistant or caregiver, or with assistance of the experimenter, in that order of preference.

8. Collect the device, charger and monitor arm.

4.5 Exit survey

1. Provide the participant with *FORM 6: Exit survey* either physically at the end of Visit 2 or digitally, have them fill it out later at their own pace, if necessary with support of a caregiver or paramedical assistant.
2. After collecting all necessary data or if this participants does not continue the study in any way, fill out *FORM 7: End of trial*.
3. Make sure to store and anonymise all collected data in a compliant way.
4. Reset the device and clear the history.

5 Action items and issues

1. Translate surveys.
2. Translate supervised experiment cues.
3. Harmonize protocol with latest version of MindSpeaker system.
4. Harmonize protocol with study needs.
5. Currently, this design does not follow participants longitudinally and does not iteratively alter and reevaluate individual solutions. Should this be incorporated and how can this be achieved in the context of the relation between the research center and patient center partners?
6. How will patients share the device within one patient center and how will we keep track of who used it how many times and to do what? Is this desirable?

Acronyms

AAC assistive and augmented communication

BCI brain-computer interface

EEG electroencephalography

EMG electromyography

LiS locked-in syndrome

UCD user-centered design

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6 Forms and instruments

Non-translated version appended below.

MindSpeaker AAC validation: Consent and eligibility

Intended for treating physician, clinical assistant or therapist

Please fill out the following details in order to recruite a participant in the study.

Study information and consent

Has informed consent been obtained?	◯ Yes ◯ No
Did the patient recieve and read the information brochure? info_brochure_en.pdf info_brochure_fr.pdf	◯ Yes ◯ No

Eligibility

Please indicate which inclusion criteria ARE NOT MET:	☐ At least 18 years old and no older than 60 years. ☐ Affected by paralysis, loss of coordination, or loss of muscle tone or other major motor impairment in a large part of the body, which affects the ability to communicate. ☐ Sufficiently informed about the purpose and course of the study. ☐ Has a (professional) caregiver willing and present to support device usage during certain sections of the study. ☐ Able to understand the experiment instructions and to cooperate. ☐ Has either dutch, english or french as mother tongue
Please indicate which of the following exclusion criteria ARE MET:	☐ A diagnosis of a major medical or psychiatric condition other than those related to my paralysis or motor impairment. ☐ A diagnosis of epilepsy. ☐ A severe, uncorrected loss of hearing. ☐ Currently using specific medications that could affect the outcome, such as neuroleptics or benzodiazepines.
Have ALL INCLUSION criteria above been met and have NONE OF THE EXCLUSION criteria been above met ?	◯ Yes ◯ No

Screening failure

Did the subject fail the participation screening?	◯ Yes ◯ No
Reason for participation screening failure:	☐ Fails to meet eligibility criteria ☐ Subject withdrawal ☐ Death ☐ Lost contact with subject ☐ Technical concerns ☐ Other
If other, please specify.	_____

MindSpeaker AAC validation: Demographics and clinical information

Intended only for treating physicians, clinical assistants or therapists!

Please fill out the form below used to collect demographic and clinical information to support the study results.

Demographics

9) Date demographics data collected

_____

10) Age

_____

11) Sex

◯ Female
◯ Male
◯ Undifferentiated
◯ Unknown

12) Handedness

◯ Left
◯ Right
◯ Ambidextrous
◯ Unknown

13) Mother tongue

◯ Dutch
◯ English
◯ French

Clinical information

14) Relevant neurological diagnosis

_____

15) Time of neurological diagnosis

_____

16) Neuro-ophthalmological, ophthalmological or oculomotor diagnosis, or qualitative description of oculomotor function according to the following dimensions:
* visual acuity
* visual fixation
* pupillary function
* eyelid function
* ocular motility
* binocular vision
* field of vision
* colour vision
* visual perception

_____

17) Date of ocular diagnosis or symptoms onset

_____

18) NSUCO oculomotor test score

_____

19) LogMAR visual acuity score _____

MindSpeaker AAC validation: Entry survey

Please complete the survey below.

Thank you!

General

20) Do you know what assistive and augmentative communication technologies are?
- ◯ Yes
- ◯ No

21) What are your expectations and needs with respect to assistive and augmentative communication technologies?

_____

22) Do you know what a brain-computer interface (BCI) is?
- ◯ Yes
- ◯ No

23) Do you know what an electroencephalogram (EEG) is?
- ◯ Yes
- ◯ No

24) Shortly describe in your own words how you think an augmentative and assistive communication device that uses brain-computer interfaces based on the electroencephalogram works.

_____

Assistive Technology Device Predisposition Assessment - Consumer (Initial)

25) Date

_____

How would you rate your functioning today in the following 9 areas when using your current assistive technology or other support (e.g. glasses for seeing)?
For items the items below, mark the best response (1 for poor through 5 for excellent).

		1	2	3	4	5
26)	Thinking, decision-making and remembering	◯	◯	◯	◯	◯
27)	Seeing	◯	◯	◯	◯	◯
28)	Hearing	◯	◯	◯	◯	◯
29)	Speaking, communicating	◯	◯	◯	◯	◯
30)	Muscle power and physical endurance	◯	◯	◯	◯	◯
31)	Control of arms, shoulders, trunk	◯	◯	◯	◯	◯
32)	Grasping and control of fingers	◯	◯	◯	◯	◯
33)	Control of hips, legs, feet	◯	◯	◯	◯	◯
34)	Mobility (getting from place to place)	◯	◯	◯	◯	◯

35) Do you use a support for any of the functionalities described above? If so, please specify the name or describe the support or device.

_____

Indicate plus [+] in the spaces where you expect to need more support over the next year (example: 'eyeglasses' gets [+] if you'll expect to need stronger corrective lenses during the next year). Indicate [-] in the spaces where you expect to need less support, and [0] where you expect your support needs should stay the same over the next year.

		[+]	[0]	[-]
36)	Thinking, decision-making and remembering	○	○	○
37)	Seeing	○	○	○
38)	Hearing	○	○	○
39)	Speaking, communicating	○	○	○
40)	Muscle power and physical endurance	○	○	○
41)	Control of arms, shoulders, trunk	○	○	○
42)	Grasping and control of fingers	○	○	○
43)	Control of hips, legs, feet	○	○	○
44)	Mobility (getting from place to place)	○	○	○

How satisfied are you currently in the following areas? For the items below, mark the best response (1 for Not Satisfied through 5 for Very Satisfied).

		1	2	3	4	5
45)	Able to go wherever desired	○	○	○	○	○
46)	Able to go wherever desired	○	○	○	○	○
47)	Self-care and domestic tasks	○	○	○	○	○
48)	Interpersonal interactions and relationships	○	○	○	○	○
49)	Close, intimate relationships	○	○	○	○	○
50)	Educational attainment	○	○	○	○	○
51)	Work and employment status/potential	○	○	○	○	○
52)	Participation in desired community, social and civic activities	○	○	○	○	○
53)	Autonomy and self-determination (making decisions)	○	○	○	○	○
54)	Fitting in, belonging, feeling connected	○	○	○	○	○
55)	Emotional well-being	○	○	○	○	○
56)	Physical comfort & well-being	○	○	○	○	○
57)	Overall health	○	○	○	○	○

58) Which 3 of the above items are most important to you?

- ☐ Able to go wherever desired
- ☐ Self-care and domestic tasks
- ☐ Interpersonal interactions and relationships
- ☐ Close, intimate relationships
- ☐ Educational attainment
- ☐ Work and employment status/potential
- ☐ Participation in desired community, social and civic activities
- ☐ Autonomy and self-determination (making decisions)
- ☐ Fitting in, belonging, feeling connected
- ☐ Emotional well-being
- ☐ Physical comfort & well-being
- ☐ Overall health

59) For your 3 most Important items, write the key personal limitations and/or external barriers you face.

_____

60) Please mark all the statements below that describe you. Mark only those that frequently or often apply to you and ignore those that very rarely or never apply to you.

- ☐ I have the support I want from family
- ☐ I have the support I want from friends
- ☐ I feel encouraged by therapists, caregivers
- ☐ I feel the general public accepts me
- ☐ I aspire to go to school or work
- ☐ I have many things I want to accomplish
- ☐ I do what my therapist(s) say without question
- ☐ I view my therapist(s) as friends, too
- ☐ I am often frustrated or overwhelmed
- ☐ I am curious & excited about new things
- ☐ I am determined to meet my goals
- ☐ I am usually calm and patient
- ☐ My life has purpose, meaning
- ☐ I am self-disciplined
- ☐ I am often angry
- ☐ I am often depressed
- ☐ I prefer to be left alone
- ☐ I am often discouraged
- ☐ I am quite resourceful
- ☐ I like having a challenge
- ☐ I am responsible & reliable
- ☐ I am generally satisfied with my life
- ☐ I find technology interesting
- ☐ I am cooperative
- ☐ I prefer a quiet lifestyle
- ☐ I often feel isolated & alone
- ☐ I accomplish what I set out to do
- ☐ I am not sure who I am now
- ☐ I want more independence
- ☐ I have a good self-image
- ☐ I often feel insecure
- ☐ I feel as if I have little privacy
- ☐ My therapist(s) know better than I what I need

MindSpeaker AAC validation: Performance evaluation

Please complete the survey below.

Thank you!

MindSpeaker software version

_____

Touch modality

Is the participant able to operate the device through touch?

◯ Yes
◯ No

Copy spelling task

Pouvez-vous m'aider à ajuster mon oreiller, s'il vous plaît ?

Aidez-moi à repositionner mon bras, il est raide.

J'aimerais savoir quand quelqu'un viendra m'aider à bouger.

Pouvez-vous me dire quel jour nous sommes aujourd'hui ?

Je veux changer de position, cette posture est fatigante.

J'aimerais aller dehors quand il fera un peu meilleur.

Rappelez-moi l'heure de mon prochain rendez-vous médical.

Je voudrais choisir mes vêtements pour demain, s'il vous plaît.

Pouvez-vous régler la hauteur de mon lit, s'il vous plaît ?

Je souhaite savoir quelles activités sont prévues cet après-midi.

Copy spelling responses (1 per line)

_____

Copy spelling AI predictions (1 per line)

_____

Copy spelling time between instruction presentation and speech synthesis (1 per line in seconds)

_____

Icon selection task

Je veux une couverture

Je voudrais un café.

Je suis en colère.

Je veux sortir.

Je veux me brosser les dents

C'est drôle.

Je souffre!

J'ai faim

Pouvez-vous répéter cela?

Je m'en fiche.

Icon selection times (one per line in seconds)

_____

Icon selection number of erroneous selections (1 target selection per line)

_____

Notes and comments

_____

Eye tracking + MindClick modality Steps to take:

- Perform onboarding procedure
- Set-up headset
- Execute spelling test, explain buttons in spelling interface
- Try to type some words (bonjour, name)
- Re-calibrate eye tracker by instructing gaze at positions
- Re-adjust MindClick parameters based on false positives, false negatives
- Explicit instruction: try to adapt your strategy to learn how to use the device

Is the participant able to perform the eye tracking + MindClick?

◯ Yes
◯ No

Copy spelling task

Pouvez-vous m'aider à ajuster mon oreiller, s'il vous plaît ?

Aidez-moi à repositionner mon bras, il est raide.

J'aimerais savoir quand quelqu'un viendra m'aider à bouger.

Pouvez-vous me dire quel jour nous sommes aujourd'hui ?

Je veux changer de position, cette posture est fatigante.

J'aimerais aller dehors quand il fera un peu meilleur.

Rappelez-moi l'heure de mon prochain rendez-vous médical.

Je voudrais choisir mes vêtements pour demain, s'il vous plaît.

Pouvez-vous régler la hauteur de mon lit, s'il vous plaît ?

Je souhaite savoir quelles activités sont prévues cet après-midi.

Copy spelling responses (1 per line)

Copy spelling AI predictions (1 per line)

Copy spelling time between instruction presentation and speech synthesis (1 per line in seconds)

Icon selection task

Bonjour comment allez-vous?

Obtenez le médecin.

Obtenez l'infirmière.

Je ne veux pas manger de pomme.

J'ai trop froid.

Je suis triste.

Pouvez-vous allumer la lumière?

J'ai des démangeaisons!

Je veux une couverture

Je veux m'allonger.

Icon selection times (one per line in seconds)

_____

Icon selection number of erroneous selections (1 target selection per line)

_____

Notes and comments

_____

Scanning + MindClick modality

Is the participant able to operate the device through scanning + MindClick?

◯ Yes
◯ No

Copy spelling task

Pouvez-vous m'aider à ajuster mon oreiller, s'il vous plaît ?

Aidez-moi à repositionner mon bras, il est raide.

J'aimerais savoir quand quelqu'un viendra m'aider à bouger.

Pouvez-vous me dire quel jour nous sommes aujourd'hui ?

Je veux changer de position, cette posture est fatigante.

J'aimerais aller dehors quand il fera un peu meilleur.

Rappelez-moi l'heure de mon prochain rendez-vous médical.

Je voudrais choisir mes vêtements pour demain, s'il vous plaît.

Pouvez-vous régler la hauteur de mon lit, s'il vous plaît ?

Je souhaite savoir quelles activités sont prévues cet après-midi.

Copy spelling responses (1 per line)

Copy spelling AI predictions (1 per line)

Copy spelling time between instruction presentation and speech synthesis (1 per line in seconds)

Icon selection task

Je ne suis pas à l'aise

Je veux un oreiller.

Demain, j'ai besoin de lire un article de presse dans un magazine.

Je veux mentir plus haut

Je veux appeler quelqu'un.

Non, merci!

Quelle heure est-il?

Arrêt!

Je veux plus.

Je ne veux pas manger de pomme.

Icon selection times (one per line in seconds)

Icon selection number of erroneous selections (1 target selection per line)

Notes and comments

Mindspeaker Aac Validation Satisfaction and workload

Please complete the survey below.

Thank you!

Overall, how satisfied are you with the device?	Completely unsatisfied	Completely satisfied
	(Place a mark on the scale above)	

Onboarding

Over all, how satisfied are you with the onboarding procedure of the device?	Completely unsatisfied	Completely satisfied
	(Place a mark on the scale above)	
Mental demand: how mentally demanding was the onboarding procedure?	Very low	Very high
	(Place a mark on the scale above)	
Physical demand: how physically demanding was the onboarding procedure?	Very low	Very high
	(Place a mark on the scale above)	
Temporal demand: how hurried or rushed was the pace of the onboarding procedure?	Very low	Very high
	(Place a mark on the scale above)	
Performance: how successful were you in the onboarding procedure?	Perfect	Failure
	(Place a mark on the scale above)	
Effort: how hard did you have to work to accomplish your level of performance in the onboarding procedure?	Very low	Very high
	(Place a mark on the scale above)	
Frustration: how insecure, discouraged, irritated, stressed, and annoyed where you during the onboarding procedure?	Very low	Very high
	(Place a mark on the scale above)	

Touch control

Did you operate the device through touch?

◯ Yes
◯ No

Over all, how satisfied are you with the device when operated through touch?

Completely unsatisfied — Completely satisfied

(Place a mark on the scale above)

Mental demand: how mentally demanding was operating the device through touch?

Very low — Very high

(Place a mark on the scale above)

Physical demand: how physically demanding was operating the device through touch?

Very low — Very high

(Place a mark on the scale above)

Temporal demand: how hurried or rushed was the pace of operating the device through touch?

Very low — Very high

(Place a mark on the scale above)

Performance: how successful were you in operating the device through touch?

Perfect — Failure

(Place a mark on the scale above)

Effort: how hard did you have to work to accomplish your level of performance in operating the device through touch?

Very low — Very high

(Place a mark on the scale above)

Frustration: how insecure, discouraged, irritated, stressed, and annoyed where you when operating the device through touch?

Very low — Very high

(Place a mark on the scale above)

Eye tracking and MindClick control

Did you operate the device through eye tracking and MindClick?

◯ Yes
◯ No

Over all, how satisfied are you with the device when operated through eye tracking and MindClick?

Completely unsatisfied — Completely satisfied

(Place a mark on the scale above)

Mental demand: how mentally demanding was operating the device through eye tracking and MindClick?

Very low — Very high

(Place a mark on the scale above)

Physical demand: how physically demanding was operating the device through eye tracking and MindClick?

Very low — Very high

(Place a mark on the scale above)

Temporal demand: how hurried or rushed was the pace of operating the device through eye tracking and MindClick?

Very low — Very high

(Place a mark on the scale above)

Effort: how hard did you have to work to accomplish your level of performance in operating the device through eye tracking and MindClick?

Very low — Very high

(Place a mark on the scale above)

Performance: how successful were you in operating the device through eye tracking and MindClick?

Perfect — Failure

(Place a mark on the scale above)

Frustration: how insecure, discouraged, irritated, stressed, and annoyed where you when operating the device through eye tracking and MindClick?

Very low — Very high

(Place a mark on the scale above)

Scanning and MindClick control

Did you operate the device through scanning and MindClick?

◯ Yes
◯ No

Over all, how satisfied are you with the device when operated through scanning and MindClick?

Completely unsatisfied — Completely satisfied

(Place a mark on the scale above)

Mental demand: how mentally demanding was operating the device through scanning and MindClick?

Very low — Very high

(Place a mark on the scale above)

Physical demand: how physically demanding was operating the device through scanning and MindClick?

Very low — Very high

(Place a mark on the scale above)

Temporal demand: how hurried or rushed was the pace of operating the device through scanning and MindClick?

Very low — Very high

(Place a mark on the scale above)

Effort: how hard did you have to work to accomplish your level of performance in operating the device through scanning and MindClick?

Very low — Very high

(Place a mark on the scale above)

Performance: how successful were you in operating the device through scanning and MindClick?

Perfect — Failure

(Place a mark on the scale above)

Frustration: how insecure, discouraged, irritated, stressed, and annoyed where you when operating the device through scanning and MindClick?

Very low Very high

(Place a mark on the scale above)

MindSpeaker AAC validation: Exit survey

Please complete the survey below.

Thank you!

General

115) Date _____

116) Mindspeaker software version _____

117) Overall, how satisfied are you with your experience with the device?

Completely dissatisfied — Completely satisfied

(Place a mark on the scale above)

118) Would you want to use this system in daily life ◯ Yes ◯ No

QUEST 2.0 survey

Please rate the following aspects of the device on their IMPORTANCE for you from 0 to 3, with 0 meaning 'not important at all' and 3 meaning 'very important'

	0	1	2	3
119) Usefulness (Degree to which the ATD is practical and helpful when performing activities in various situations and environments)	◯	◯	◯	◯
120) Repairs/servicing (Degree of ease in having the ATD repaired and serviced)	◯	◯	◯	◯
121) Adjustments (Degree of ease in setting and adjusting the components of the ATD.)	◯	◯	◯	◯
122) Training (Degree ot skill and experience required before being able to use the ATD)	◯	◯	◯	◯
123) Support from family/peers/employer (Degree of social support from others regarding the use of the ATD)	◯	◯	◯	◯
124) Durability (Degree of robustness and sturdiness of the ATD.)	◯	◯	◯	◯

125)

Accommodation by others (Degree of ease with which other persons adjust and adapt to the ATD.)	○	○	○	○
126) Safety (Degree to which the ATD is safe, secure and harmless.)	○	○	○	○
127) Comfort (Degree of physical and psychological well-being associated with use of the ATD.)	○	○	○	○
128) Dimensions (Degree of convenience of the device's size when using, transporting and/or storing the ATD.)	○	○	○	○
129) Simplicity of use (Degree to which the ATD is simple and easy to set-up and use.)	○	○	○	○
130) Follow-up services (Degree of ease in obtaining ongoing support services for ATD related difficulties that occur in and outside the home.)	○	○	○	○
131) Professional assistance (Degree to which the professionals involved in the device selection/training are accessible and competent.)	○	○	○	○
132) Appearance (Degree of attractiveness of the ATD with respect to its design, form, color and acceptability.)	○	○	○	○
133) Compatibility (Degree of suitability of the ATD with respect to the use of other technologies and to the nature of the setting/environment.)	○	○	○	○
134) Effort (Degree of physical and/or psychological exertion required to use the ATD.)	○	○	○	○
135) Maintenance (Degree to which upkeep and care of the ATD is affordable and easy to obtain.)	○	○	○	○
136) Reaction of others (Degree to which others encourage use of the ATD as shown by their positive attitude and realistic expectations.)	○	○	○	○

137)

Weight (Degree to which the ATD is lightweight and easy to use, lift and/or move.)	○	○	○	○
138) Functional performance (Degree to which the ATD enhances/increases independence in self-help, work or leisure activities.)	○	○	○	○
139) Transportability (Degree to which the ATD is convenient to transport via the desired means of transportation.)	○	○	○	○
140) Flexibility (Degree to which the ATD is multipurposeful, versatile and/or adaptable.)	○	○	○	○
141) Service delivery (Degree of ease with which the ATD was acquired, including the length of time required to obtain the device.)	○	○	○	○
142) Personal acceptance (Degree to which the person is motivated and accepts to use the ATD in private and/or in public.)	○	○	○	○
143) Cost (Degree to which the expenses associated with purchasing, maintaining and repairing the ATD are affordable, reasonable and worthwhile.)	○	○	○	○
144) Installation (Degree of ease to assemble, install and/or set-up the ATD.)	○	○	○	○
145) Effectiveness (Degree to which the ATD is valuable to goal achievement.)	○	○	○	○

Please rate the following aspects of the device on how SATISFIED you are with them from 0 to 5, with 0 meaning 'completely dissatisfied' and 5 meaning 'completely satisfied'

	0	1	2	3	4	5
146) Usefulness (Degree to which the ATD is practical and helpful when performing activities in various situations and environments)	○	○	○	○	○	○

147)

Repairs/servicing (Degree of ease in having the ATD repaired and serviced)	○	○	○	○	○	○
148) Adjustments (Degree of ease in setting and adjusting the components of the ATD.)	○	○	○	○	○	○
149) Training (Degree ot skill and experience required before being able to use the ATD)	○	○	○	○	○	○
150) Support from family/peers/employer (Degree of social support from others regarding the use of the ATD)	○	○	○	○	○	○
151) Durability (Degree of robustness and sturdiness of the ATD.)	○	○	○	○	○	○
152) Accommodation by others (Degree of ease with which other persons adjust and adapt to the ATD.)	○	○	○	○	○	○
153) Safety (Degree to which the ATD is safe, secure and harmless.)	○	○	○	○	○	○
154) Comfort (Degree of physical and psychological well-being associated with use of the ATD.)	○	○	○	○	○	○
155) Dimensions (Degree of convenience of the device's size when using, transporting and/or storing the ATD.)	○	○	○	○	○	○
156) Simplicity of use (Degree to which the ATD is simple and easy to set-up and use.)	○	○	○	○	○	○
157) Follow-up services (Degree of ease in obtaining ongoing support services for ATD related difficulties that occur in and outside the home.)	○	○	○	○	○	○
158) Professional assistance (Degree to which the professionals involved in the device selection/training are accessible and competent.)	○	○	○	○	○	○
159) Appearance (Degree of attractiveness of the ATD with respect to its design, form, color and acceptability.)	○	○	○	○	○	○

160)

Compatibility (Degree of suitability of the ATD with respect to the use of other technologies and to the nature of the setting/environment.)	○	○	○	○	○	○
161) Effort (Degree of physical and/or psychological exertion required to use the ATD.)	○	○	○	○	○	○
162) Maintenance (Degree to which upkeep and care of the ATD is affordable and easy to obtain.)	○	○	○	○	○	○
163) Reaction of others (Degree to which others encourage use of the ATD as shown by their positive attitude and realistic expectations.)	○	○	○	○	○	○
164) Weight (Degree to which the ATD is lightweight and easy to use, lift and/or move.)	○	○	○	○	○	○
165) Functional performance (Degree to which the ATD enhances/increases independence in self-help, work or leisure activities.)	○	○	○	○	○	○
166) Transportability (Degree to which the ATD is convenient to transport via the desired means of transportation.)	○	○	○	○	○	○
167) Flexibility (Degree to which the ATD is multipurposeful, versatile and/or adaptable.)	○	○	○	○	○	○
168) Service delivery (Degree of ease with which the ATD was acquired, including the length of time required to obtain the device.)	○	○	○	○	○	○
169) Personal acceptance (Degree to which the person is motivated and accepts to use the ATD in private and/or in public.)	○	○	○	○	○	○
170) Cost (Degree to which the expenses associated with purchasing, maintaining and repairing the ATD are affordable, reasonable and worthwhile.)	○	○	○	○	○	○

171)

Installation (Degree of ease to assemble, install and/or set-up the ATD.)	○	○	○	○	○	○
172) Effectiveness (Degree to which the ATD is valuable to goal achievement.)	○	○	○	○	○	○

SUS questionnaire

Please rate the extent to which you agree with the following statements, with 1 meaning 'strongly disagree' and 5 meaning 'stronly agree'

	1	2	3	4	5
173) I think that I would like to use this system frequently.	○	○	○	○	○
174) I found the system unnecessarily complex.	○	○	○	○	○
175) I thought the system was easy to use.	○	○	○	○	○
176) I think that I would need the support of a technical person to be able to use this system.	○	○	○	○	○
177) I found the various functions in this system were well integrated.	○	○	○	○	○
178) I thought there was too much inconsistency in this system.	○	○	○	○	○
179) I would imagine that most people would learn to use this system very quickly.	○	○	○	○	○
180) I found the system very cumbersome to use.	○	○	○	○	○
181) I felt very confident using the system.	○	○	○	○	○
182) I needed to learn a lot of things before I could get going with this system.	○	○	○	○	○

ATD-PA questionnaire

How would you rate your functioning today in the following 9 areas when using your current assistive technology or other support (e.g. glasses for seeing)?
For items the items below, mark the best response (1 for poor through 5 for excellent).

	1	2	3	4	5
183) Thinking, decision-making and remembering	○	○	○	○	○

184)

Seeing	○	○	○	○	○
185) Hearing	○	○	○	○	○
186) Speaking, communicating	○	○	○	○	○
187) Muscle power and physical endurance	○	○	○	○	○
188) Control of arms, shoulders, trunk	○	○	○	○	○
189) Grasping and control of fingers	○	○	○	○	○
190) Control of hips, legs, feet	○	○	○	○	○
191) Mobility (getting from place to place)	○	○	○	○	○

192) Do you use a support for any of the functionalities described above? If so, please specify the name or describe the support or device. _____

Indicate plus [+] in the spaces where you expect to need more support over the next year (example: 'eyeglasses' gets [+] if you'll expect to need stronger corrective lenses during the next year). Indicate [-] in the spaces where you expect to need less support, and [0] where you expect your support needs should stay the same over the next year.

	[+]	[0]	[-]
193) Thinking, decision-making and remembering	○	○	○
194) Seeing	○	○	○
195) Hearing	○	○	○
196) Speaking, communicating	○	○	○
197) Muscle power and physical endurance	○	○	○
198) Control of arms, shoulders, trunk	○	○	○
199) Grasping and control of fingers	○	○	○
200) Control of hips, legs, feet	○	○	○
201) Mobility (getting from place to place)	○	○	○

How satisfied are you currently in the following areas? For the items below, mark the best response (1 for Not Satisfied through 5 for Very Satisfied).

	1	2	3	4	5
202) Able to go wherever desired	○	○	○	○	○
203) Able to go wherever desired	○	○	○	○	○
204) Self-care and domestic tasks	○	○	○	○	○
205) Interpersonal interactions and relationships	○	○	○	○	○
206) Close, intimate relationships	○	○	○	○	○

207)

Educational attainment	○	○	○	○	○
208) Work and employment status/potential	○	○	○	○	○
209) Participation in desired community, social and civic activities	○	○	○	○	○
210) Autonomy and self-determination (making decisions)	○	○	○	○	○
211) Fitting in, belonging, feeling connected	○	○	○	○	○
212) Emotional well-being	○	○	○	○	○
213) Physical comfort & well-being	○	○	○	○	○
214) Overall health	○	○	○	○	○

---

215) Which 3 of the above items are most important to you?

- ☐ Able to go wherever desired
- ☐ Self-care and domestic tasks
- ☐ Interpersonal interactions and relationships
- ☐ Close, intimate relationships
- ☐ Educational attainment
- ☐ Work and employment status/potential
- ☐ Participation in desired community, social and civic activities
- ☐ Autonomy and self-determination (making decisions)
- ☐ Fitting in, belonging, feeling connected
- ☐ Emotional well-being
- ☐ Physical comfort & well-being
- ☐ Overall health

216) Please mark all the statements below that describe you. Mark only those that frequently or often apply to you and ignore those that very rarely or never apply to you.

- ☐ I have the support I want from family
- ☐ I have the support I want from friends
- ☐ I feel encouraged by therapists, caregivers
- ☐ I feel the general public accepts me
- ☐ I aspire to go to school or work
- ☐ I have many things I want to accomplish
- ☐ I do what my therapist(s) say without question
- ☐ I view my therapist(s) as friends, too
- ☐ I am often frustrated or overwhelmed
- ☐ I am curious & excited about new things
- ☐ I am determined to meet my goals
- ☐ I am usually calm and patient
- ☐ My life has purpose, meaning
- ☐ I am self-disciplined
- ☐ I am often angry
- ☐ I am often depressed
- ☐ I prefer to be left alone
- ☐ I am often discouraged
- ☐ I am quite resourceful
- ☐ I like having a challenge
- ☐ I am responsible & reliable
- ☐ I am generally satisfied with my life
- ☐ I find technology interesting
- ☐ I am cooperative
- ☐ I prefer a quiet lifestyle
- ☐ I often feel isolated & alone
- ☐ I accomplish what I set out to do
- ☐ I am not sure who I am now
- ☐ I want more independence
- ☐ I have a good self-image
- ☐ I often feel insecure
- ☐ I feel as if I have little privacy
- ☐ My therapist(s) know better than I what I need

Please rate device on the items below according to the following scale

5 = All the time (100% of the time)

4 = Often (around 75% of the time)

3 = Half the time, neutral (about 50% of the time)

2 = Sometimes (around 25% of the time)

1 = Not at all (0% of the time)

0 = Not applicable

	0	1	2	3	4	5
217) This device is helping me to achieve my goals (including the primary goals written above).	○	○	○	○	○	○
218) This device is benefiting me and improving my quality of life.	○	○	○	○	○	○
219) I know how to use this device and its various features.	○	○	○	○	○	○

220)

I feel more secure (safe, sure of myself) when using this device.	○	○	○	○	○	○
221) This device fits well with my accustomed routine.	○	○	○	○	○	○
222) I have the capabilities and stamina to use this device without discomfort, stress and fatigue.	○	○	○	○	○	○
223) The supports, assistance and accommodations exist for successful use of this device.	○	○	○	○	○	○
224) This device physically fits in all desired environments (purse, pocket, desk, car, etc.).	○	○	○	○	○	○
225) I feel comfortable (and not self-conscious) using this device around family.	○	○	○	○	○	○
226) I feel comfortable (and not self-conscious) using this device around friends.	○	○	○	○	○	○
227) I feel comfortable (and not self-conscious) using this device at school or work.	○	○	○	○	○	○
228) I feel comfortable (and not self-conscious) using this device around the community.)	○	○	○	○	○	○

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229) Please indicate the 3 (THREE) items that are most important to you.

- ☐ This device is helping me to achieve my goals (including the primary goals written above).
- ☐ This device is benefiting me and improving my quality of life.
- ☐ I know how to use this device and its various features.
- ☐ I feel more secure (safe, sure of myself) when using this device.
- ☐ This device fits well with my accustomed routine.
- ☐ I have the capabilities and stamina to use this device without discomfort, stress and fatigue.
- ☐ The supports, assistance and accommodations exist for successful use of this device.
- ☐ This device physically fits in all desired environments (purse, pocket, desk, car, etc.).
- ☐ I feel comfortable (and not self-conscious) using this device around family.
- ☐ I feel comfortable (and not self-conscious) using this device around friends.
- ☐ I feel comfortable (and not self-conscious) using this device at school or work.
- ☐ I feel comfortable (and not self-conscious) using this device around the community.

Open comments

230) Do you have any other feedback or comments or did you experience any other specific issues during device usage?

231) Does your caregiver/therapist/person who assisted with device setup have any other feedback or comments or did you experience any other specific issues during device usage?

End of Trial

eCRF version X.0 - Protocol version X.0

END OF TRIAL

Date End of Trial study visit	_____
Primary reason for trial participation termination	◯ Subject completed study as per protocol ◯ Physician decision ◯ Subject decision (withdrew consent) ◯ Lost contact with subject ◯ Adverse Event ◯ Death ◯ Major protocol deviation ◯ Other
Date of death	_____ (Please ensure to update Adverse Event page)
If "Other" reason for trial participation termination, please specify	_____