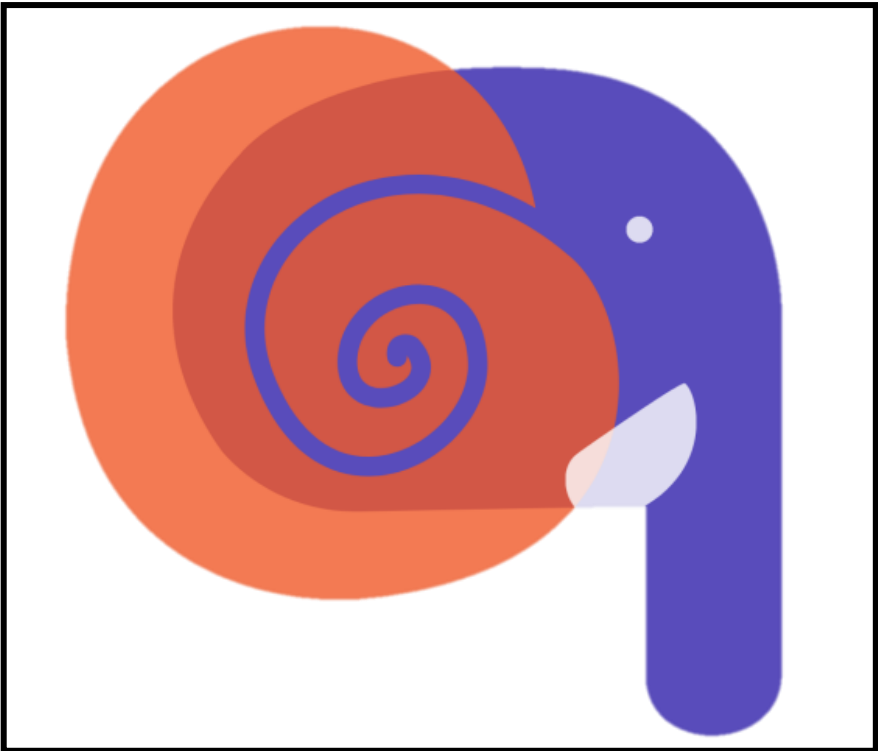


Case Report Form (CRF)

Study number: METC 18-028

Study title: ELEctric Place-pitched Hearing Achieves Natural Tonotopy (ELEPHANT)

Study site: Maastricht MUMC +



ELEPHANT-study

CRF Instructions

1. Verify if informed consent form (separate IC document) is signed by both patient and researcher before inclusion starts. The IC form should be locked and stored separate from this CRF. A signed copy of the IC form is given to the patient. An IC note is made to the patient's electronic medical dossier (SAP).
2. All questions in this CRF should be filled in, preferably with black ink.
3. The patient identification number (defined at p. 4) should be noted on every page of the CRF.
4. If data needs to be corrected, then these revisions should be provided with addition of a name and signature of the researcher. Corrected data should be crossed through but needs to stay readable. No correction fluid should be used.
5. When a test condition has been assessed, the corresponding box should be checked by an X.
6. If a test condition is not applicable, and thereby not assessed, the corresponding box should be crossed out.
7. If a test condition is applicable, but was not assessed, the corresponding box should be checked by an O.
8. Dates should be filled in using the format date/month/year: DD/MM/(20)YY

Glossary

CI: cochlear implant

- Standard program:
frequency-allocation table is mapped conventionally, following clinical routine, based on a one-size fits-all principle, programmed on either processor Δ or \bigcirc .
- Natural program:
frequency-allocation table is mapped experimentally, following individual natural tonotopy, based on imaging data, programmed on either processor Δ or \bigcirc .
- Preferred program :
either standard or natural map, as decided by shared decision making during visit F14 (week 26).

HA: hearing aid

- Bimodal fit:
settings that are programmed conventionally, following clinical gain rules based on patient's audiogram.
- Loudness fit:
settings that are programmed experimentally, based on the acoustic loudness growth between threshold (T) and maximum (M) level.

Overall

- Clinical program:
CI frequency-allocation table or HA settings that are mapped according to the obtained preferences during the study period, but programmed with clinical software.

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

INFORMED CONSENT

Subject ID:

E	P		
---	---	--	--

Year of birth:

--	--	--	--

Date of subject's written informed consent:/...../.....

Inclusion Criteria	Yes	No*
adult (>18 years of age) and meeting the Dutch standard CI criteria	<input type="checkbox"/>	<input type="checkbox"/>
proficient speaker of Dutch language	<input type="checkbox"/>	<input type="checkbox"/>
post-lingual onset of profound deafness (> 4 years of age)	<input type="checkbox"/>	<input type="checkbox"/>
subject receives an Advanced Bionics HiRes Ultra implant with Midscale electrode and an Advanced Bionics processor	<input type="checkbox"/>	<input type="checkbox"/>
prepared to use study specific hearing aid (Phonak) for the duration of the study (in case of contralateral HA)	<input type="checkbox"/>	<input type="checkbox"/>
rehabilitation at MUMC+ for the first year after surgery regarding CI as well as HA	<input type="checkbox"/>	<input type="checkbox"/>
active participation in trial related procedures such as daily randomization and regular testing	<input type="checkbox"/>	<input type="checkbox"/>
agreed to participate in this part of the study (by informed consent)	<input type="checkbox"/>	<input type="checkbox"/>

*If any inclusion criteria are ticked no then the patient is not eligible for the study.

Exclusion Criteria	Yes*	No
physical or non-physical contraindications for MRI or CT imaging	<input type="checkbox"/>	<input type="checkbox"/>
additional disabilities that may prevent active participation**	<input type="checkbox"/>	<input type="checkbox"/>
cochlear or neural abnormalities that could affect outcome measures and/or compromise the placement of the electrode array as assessed by the CI surgeon	<input type="checkbox"/>	<input type="checkbox"/>
active participation in another prospective clinical trial	<input type="checkbox"/>	<input type="checkbox"/>
pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
requirement of electric-acoustic activation prior to the first year follow-up	<input type="checkbox"/>	<input type="checkbox"/>
having received a cochlear implant earlier (e.g. explantation or bilateral implantation)	<input type="checkbox"/>	<input type="checkbox"/>

* If any exclusion criteria are ticked yes then the patient is not eligible for the study.

** If there are indications that the mental abilities to comply with the study procedures are insufficient, additional screening will be performed with the Mini-Mental State Examination. Patients will be excluded from the study when the resulting score is lower than 24;

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

BASELINE DATA

LEFT hearing situation

- Etiology of deafness
- Onset of profound deafness (age)
- Current HA-use?
 - If yes, since age
 - If yes, brand and type device
 - If yes, age current device
 - If yes, frequency of usage

<input type="checkbox"/> Unknown/Progressive	
<input type="checkbox"/> Other:	
Yes / No	
years	
< 5 / 5-10 / > 10	hours/day

RIGHT hearing situation

- Etiology of deafness
- Onset of profound deafness (age)
- Current HA-use?
 - If yes, since age
 - If yes, brand and type device
 - If yes, age current device
 - If yes, frequency of usage

<input type="checkbox"/> Unknown/Progressive	
<input type="checkbox"/> Other:	
Yes / No	
years	
< 5 / 5-10 / > 10	hours/day

Tinnitus Questionnaire (TQ)

- Total score
- Grade

1 / 2 / 3 / 4

Overall

- Education level
- Native language
 - If other, Dutch language level
- Current use of medication
 - If yes, type, dose and indication

<input type="checkbox"/> None
<input type="checkbox"/> Primary school
<input type="checkbox"/> Special education
<input type="checkbox"/> LBO/LTS
<input type="checkbox"/> ULO/MBO/MAVO
<input type="checkbox"/> HAVO/VWO
<input type="checkbox"/> HBO/HEAO/HTS
<input type="checkbox"/> Higher science education
Dutch / other:
Very good / good / average / limited
Yes / No

1. Pre-fit phase

1.1. P1/P2: Candidacy visits (and pre-OP, if applicable)

1.1.1. IMAGING

CT performed? Yes, date: No

MRI performed? Yes, date: No

Remarks

1.1.2. TONE AUDIOMETRY

	Unaided		HA		Unaided retest	
Date/...../.....	/...../.....	/...../.....	
Ear	L	R	L	R	L	R
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

1.1.3. SPEECH AUDIOMETRY

	Unaided		HA		Unaided retest	
Date/...../.....	/...../.....	/...../.....	
Ear	L	R	L	R	L	R
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

1.1.4. REM

REM performed? Yes, date: No, because.....

HA refit necessary? No Yes, refit on date:

Retest after refit? No Yes, retest on date:

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

	Tone audio		Speech audio	
	HA		HA	
Ear	L	R	L	R
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

1.1.5. EARMOULD

Adequate earmould available for contralateral ear? Yes, date: No, describe in remarks

If not, prescription given? Yes, date: No

Remarks

1.1.6. QUESTIONNAIRES

	Given to subject	Returned and checked
Date/...../...../...../.....
SSQ-12 (I07)	<input type="checkbox"/>	<input type="checkbox"/>
HUI-3 (I08)	<input type="checkbox"/>	<input type="checkbox"/>
ICECAP-A (09)	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

1.1.7. HARDWARE

Patient choice for CI color? Silver gray Chestnut
 Sand beige Velvet black
 Alpine white

- Patient choice for HA color? Silver gray Chestnut
 Sand beige Velvet black
 Graphite grey

Remarks

1.1.8. PROTOCOL DEVIATIONS

- Were there any protocol deviations? Yes No

Remarks

General remarks

1.2. P3: Visit OR

Date:

...../...../.....

1.2.1. IMPLANTATION REPORT

Implantation report (I01) completed and signed by surgeon? Yes No

Intraoperative measurements performed? Yes No

Particularities that will influence CI fitting? No Yes, describe in remarks and note on CRF in section 2.1.1 and 2.2.2!

Remarks

.....

1.2.2. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

.....

General remarks

.....

1.3. P4: Visit CBCT

Date:

1.3.1. VISIT ENT

Any particularities? No Yes, describe:
.....
.....

1.3.2. CBCT SCAN

CBCT scan performed? Yes No, because..... → EARLY TERMINATION!
Scan quality adequate? Yes No, new scan performed on/...../.....
Particularities that will influence CI fitting? No Yes, describe in remarks and note on CRF in section 2.1.1 and 2.2.2!

Remarks

.....
.....

1.3.3. EARMOULD

Adequate earmould available for contralateral ear?
 Yes No, describe steps to be taken before visit F1:
.....
.....

1.3.4. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....
.....

1.3.5. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

.....
.....

1.3.6. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

General remarks

2. First phase

2.1. Pre-fitting preparation

2.1.1. MAPPING

Mapping performed? Yes, date: No

Electrodes extracochlear? No Yes, el.....

Electrodes folded over in tip? No Yes, el.....

Impedances within normal range ($1.0\text{ k}\Omega \leq \text{value} \leq 30.0\text{ k}\Omega$)?

El number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Y(es)/N(o)																

Electrodes to be turned off (based on impedances)? No Yes, el.....

→ To be applied in standard AND natural map!

→ Note on section 2.2.2 and first fitting form!

Number of channels mapped < 8598 Hz (excluding phantom)? ≥ 8 < 8 → EARLY TERMINATION!

Remarks

2.1.2. DAILY RANDOMIZATION

Randomization schedule created? Yes, date: No

Any particularities? No Yes, describe:

.....

.....

Remarks

2.1.3. TEST RANDOMIZATION

Randomization of test conditions and word lists performed? Yes, date: No

Any particularities? No Yes, describe:

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

.....
Remarks

2.1.4. HARDWARE

- Patient kit ready? Yes, date:/...../..... No
- Patient processor stored safely? Yes, date:/...../..... No
- Contralateral earmould available? Yes, date:/...../..... No

	CI		HA
Device	Research CI Naida Q70 △	Research Naida Q70 ○	Research Naida Link
Serial number
Color

Remarks

2.1.5. SOFTWARE

- Measurement template ready in BEPS+? Yes, date:/...../..... No
- Natural template ready in BEPS+? Yes, date:/...../..... No
- Audiogram ready in Phonak Target? Yes, date:/...../..... No

Remarks

2.2. Visit F1 (wk 0)

Date:

Bimodal user: Yes No, because.....

2.2.1. TONE AUDIOMETRY

	Unaided	
Ear	L	R
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Decided to start with EAS? No Yes → EARLY TERMINATION!

Remarks

.....

2.2.2. SPEECH AUDIOMETRY

	Unaided	
Ear	L	R
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.2.3. FITTING

Particularities to be taken into account during fitting:

from impedance measurements? No Yes,

from ECAP measurements? No Yes,

from CBCT scan? No Yes,

Fitting form (i02) completed? No Yes

Particularities relevant for next fitting? No Yes, see fitting form.

Remarks

.....

BREAK

2.2.4. SPEECH AUDIOMETRY

	Test			Retest			Test			Retest					
Listening	CI			CI			CI			HA					
CI processor	△			△			○			○					
CI program								
HA program	HA turned off									Bimodal fit					
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65	75	65	55
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Additional testing performed with number lists

2.2.5. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA turned off									
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.	
Order	1		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Could not be performed (too difficult for patient)

2.2.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Not performed, due to matrix in quiet SRT score = < 50%

2.2.7. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.2.8. DATA MANAGEMENT CHECK-UP

Digital data complete and correctly archived on network drive? Yes No

→ If no, describe steps to be taken:

.....

.....

Source documents correctly archived in filing cabinet? Yes No

→ If no, describe steps to be taken:

.....

.....

Remarks

.....

2.2.9. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.2.10. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.2.11. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Any signs of tinnitus? Yes No

If yes, on what side(s) Left Right

If yes, to what extent (VAS 0-10)? Left: Right:

Any signs of vertigo? Yes No

Any signs of oscillopsia? Yes No

Remarks

General remarks

2.3. Visit F2 (week 1)

Date:

Bimodal user: Yes No, because.....

2.3.1. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.3.2. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Fitting form (i02) completed? Yes No

Particularities relevant for next fitting? No Yes, note on fitting form

Compliance forms completed? Yes No

ECAP completed? Yes No

Remarks

.....

2.3.3. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

.....

BREAK

2.3.4. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest
Listening	CI			CI		CI			CI
CI processor	△			△		○			○
CI program				
HA program	HA turned off								
Level (dB SPL)	75	65	55	65	75	65	55	65	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Remarks

Additional testing performed with number lists

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.3.5. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.3.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Not performed, due to matrix in quiet SRT score = < 50%

2.3.7. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.3.8. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.3.9. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.4. Visit F3 (week 2)

Date:

Bimodal user: Yes No, because.....

2.4.1. TONE AUDIOMETRY

	CI		HA
Processor	△	○	Bimodal fit
CI program	CI off
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.4.2. REM

Test completed? No Yes
 Changes made to HA settings as a result of REM? No Yes, see fitting form

Remarks

2.4.3. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.4.4. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form
 Fitting form (i02) completed? Yes No
 Particularities relevant for next fitting? No Yes, note on fitting form
 Compliance forms completed? Yes No

Remarks

2.4.5. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

BREAK

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.4.6. QUESTIONNAIRES

	Given to subject	To be returned
Date/...../.....	Visit F4
Sound quality descriptors (I11)	<input type="checkbox"/>	

Remarks

.....

2.4.7. SPEECH AUDIOMETRY

	Test			Retest			Test			Retest		
Listening	CI			CI			CI			HA		
CI	△			△			○			○		
CI program			CI turned off					
HA program	HA turned off						Bimodal fit					
Level (dB)	75	65	55	65	75	65	55	65	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Additional testing performed with number lists

2.4.8. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA turned off									
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.4.9. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

Not performed, due to matrix in quiet SRT score = < 50%

2.4.10. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.4.11. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.4.12. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.5. Visit F4 (week 3)

Date:

Bimodal user: Yes No, because.....

2.5.1. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.5.2. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Fitting form (i02) completed? Yes No

Particularities relevant for next fitting? No Yes, note on fitting form

Compliance forms completed? Yes No

Consequences of CI compliance measurements, based on calculations (fitting form) and cut-off points (Appendix Compliance):

Study continuation Early termination and transfer to clinical care

Remarks

2.5.3. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

2.5.4. SPEECH AUDIOMETRY

	Test			Retest			Test			Retest			Test		Retest	
Listening	CI			CI			CI			CI			HA		HA	
CI processor	△			△			○			○			CI turned off			
CI program						CI turned off			
HA program	HA turned off												Bimodal fit			
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65	75	65	55	

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Test			Retest		Test			Retest			
Listening	CIHA			CIHA		CIHA			CIHA			
CI processor	△			△		○			○			
CI program						
HA program	Bimodal fit											
Level (dB SPL)	55	65	75	65	55	65	75	65				
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.5.5. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA turned off									
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

BREAK

2.5.6. QUESTIONNAIRES

	Returned and checked?
Date/...../.....
Sound quality descriptors (I11)	<input type="checkbox"/>

Remarks

.....

2.5.7. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA	CI	CI	CIHA	CIHA
CI processor	△ / ○		△	△	△	△	○	○	○	○
CI program	
HA program	Off / bim		HA off		Bimodal	Bimodal	HA off		Bimodal	Bimodal
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)	

Remarks

Not performed, due to matrix in quiet SRT score = < 50%

.....

2.5.8. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.5.9. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.5.10. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

2.6. Visit F5 (week 4)

Date:

Bimodal user: Yes No, because.....

2.6.1. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

.....

2.6.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.6.3. CHECK-UP FITTING

Preference scales (i03) completed? Yes No

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

Remarks

.....

2.6.4. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest			
Listening	CI			CI		CI			CI			
CI processor	△			△		○			○			
CI program							
HA program	HA turned off											
Level (dB SPL)	75	65	55	65	75	65	55	65				
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Remarks

.....

2.6.5. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1		2	3	4	5
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.6.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1		2	3	4	5
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

Remarks

Not performed, due to matrix in quiet SRT score = < 50%

BREAK

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.6.7. LISTENING EFFORT

	Practice	Test	Test	Test	Test
Listening	CI	CI	CI	CIHA	CIHA
CI processor	△ / ○	△	○	△	○
CI program
HA program	Off / bimodal	HA off		Bimodal fit	Bimodal fit
N	1	5	5	5	5
SRT input (in dB SNR)
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.6.8. LOUDNESS SCALING

	Test	Test	Test
Listening	CI	CI	HA
CI processor	△	○	
CI program	CI off
HA program	HA off		Bimodal fit
N frequencies	4	4	4
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.6.9. SMRT

	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI
CI processor	△	△	○	○
CI program	
HA program	HA turned off			
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.6.10. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.6.11. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.6.12. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

2.7. Visit F6 (week 5)

Date:

Bimodal user: Yes No, because.....

2.7.1. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

.....

2.7.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.7.3. CHECK-UP FITTING

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

Remarks

.....

BREAK

2.7.4. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest	
Listening	CI			CI		CI			CI	
CI processor	△			△		○			○	
CI program					
HA program	HA turned off									
Level (dB SPL)	75	65	55	65	75	65	55	65		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.7.5. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1		2	3	4	5
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.7.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks
 Not performed, due to matrix in quiet SRT score = < 50%

2.7.7. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.7.8. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.7.9. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.8. Visit F7 (week 6)

Date:

Bimodal user: Yes No, because.....

2.8.1. TONE AUDIOMETRY

	CI	
Program	△	○
CI program
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.8.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.8.3. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Particularities relevant for next fitting? No Yes, note on fitting form

Fitting form (i02) completed? Yes No

Compliance forms completed? Yes No

Consequences of CI compliance measurements, based on calculations (fitting form) and cut-off points

(Appendix Compliance):

Study continuation Removed from CI per protocol population

Early terminated and transferred to clinical care

Consequences of HA compliance measurements, based on calculations (fitting form) and cut-off points

(Appendix Compliance):

Study continuation No bimodal testing at F10 → Check 'No bimodal user at 2.10'

Remarks

2.8.4. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

.....
Remarks

BREAK

2.8.5. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest	
Listening	CI			CI		CI			CI	
CI processor	△			△		○			○	
CI program					
HA program	HA turned off									
Level (dB SPL)	75	65	55	65	75	65	55	65		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.8.6. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA turned off									
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.
Order	1		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.8.7. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.8.8. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.8.9. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.8.10. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.9. Visit F8 (week 7)

Date:

Bimodal user: Yes No, because.....

2.9.1. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

.....

2.9.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.9.3. CHECK-UP FITTING

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

Remarks

.....

BREAK

2.9.4. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest	
Listening	CI			CI		CI			CI	
CI processor	△			△		○			○	
CI program					
HA program	HA turned off									
Level (dB SPL)	75	65	55	65	75	65	55	65		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.9.5. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.9.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.9.7. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.9.8. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.10. Visit F9 (week 8)

Date:

Bimodal user: Yes No, because.....

2.10.1. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

2.10.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.10.3. CHECK-UP FITTING

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

ECAP measured? Yes No

Remarks

2.10.4. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest	
Listening	CI			CI		CI			CI	
CI processor	△			△		○			○	
CI program					
HA program	HA turned off									
Level (dB SPL)	75	65	55	65	75	65	55	65		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.10.5. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.10.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1		2	3	4	5
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.10.7. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.10.8. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.10.9. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.11. Visit F10 (week 10)

Date:

Bimodal user: Yes No, because.....

2.11.1. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

Remarks

.....

2.11.2. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.11.3. CHECK-UP FITTING

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

Remarks

.....

2.11.4. QUESTIONNAIRES

	Given to subject	To be returned
Date/...../.....	Visit F11
Sound quality descriptors (I11)	<input type="checkbox"/>	

Remarks

.....

2.11.5. SPEECH AUDIOMETRY

	Test			Retest			Test			Retest		
Listening	CI			CI			CI			HA		
CI processor	△			△			○			○		
CI program					
HA program	HA turned off									Bimodal fit		
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Test			Retest	Test			Retest				
Listening	CIHA			CIHA	CIHA			CIHA				
CI processor	△			△	○			○				
CI program							
HA program	Bimodal fit											
Level (dB SPL)	55	65	75	65	55	65	75	65				
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

Remarks










BREAK

2.11.6. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

















2.11.7. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA	CI	CI	CIHA	CIHA
CI processor										
CI program	
HA program	Off / bimodal		HA turned off		Bimodal fit	Bimodal fit	HA turned off		Bimodal fit	Bimodal fit
N sentences	10	10	10	10	10	10	10	10	10	10
Word list
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)	

Remarks

BREAK

2.11.8. MATRIX IN NOISE SPATIAL

	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI	CI	CI	CI	CI
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor								
CI program	
HA program	HA turned off							
N sentences	10	10	10	10	10	10	10	10
Hammerfall
Word list
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CIHA	CIHA	CIHA	CIHA	CIHA	CIHA	CIHA	CIHA
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor								
CI program	
HA program	Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit
N sentences	10	10	10	10	10	10	10	10
Preset
Word list
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.11.9. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.11.10. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.11.11. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.12. Visit F11 (week 12)

Date:

Bimodal user: Yes No, because.....

2.12.1. LISTENING EFFORT

	Practice	Test	Test	Test	Test
Listening	CI / CIHA	CI	CI	CIHA	CIHA
CI processor	△ / ○	△	○	△	○
CI program
HA program	Off / bimodal	HA off		Bimodal fit	Bimodal fit
N	1	5	5	5	5
SRT input (in dB SNR) -> See visit F10
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.12.2. LOUDNESS SCALING

	Test	Test	Test
Listening	CI	CI	HA
CI processor	△	○	
CI program	CI off
HA program	HA off		Bimodal fit
N frequencies	4	4	4
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.12.3. SMRT

	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI
CI processor	△	△	○	○
CI program	
HA program	HA turned off			
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.12.4. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.12.5. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Fitting form (i02) completed? Yes No

Particularities relevant for next fitting? No Yes, note on fitting form

Compliance forms completed? Yes No

Consequences of CI compliance measurements, based on calculations (fitting form) and cut-off points (Appendix Compliance):

- Study continuation Removed from CI per protocol population
- Early terminated and transferred to clinical care

Remarks

.....

2.12.6. SPEECH THERAPY

Particularities from speech therapy to be taken into account? No Yes, note here

.....

Remarks

.....

BREAK

2.12.7. SPEECH AUDIOMETRY

	Test			Retest	Test			Retest
Listening	CI			CI	CI			CI
CI processor	△			△	○			○
CI program				
HA program	HA turned off							
Level (dB SPL)	75	65	55	65	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.12.8. MATRIX IN QUIET

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.12.9. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

Remarks

BREAK

2.12.10. QUESTIONNAIRES

	Returned and checked?
Date/...../.....
Sound quality descriptors (I11)	<input type="checkbox"/>

Remarks

2.12.11. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.12.12. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.12.13. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.13. Visit F12 (week 16)

Date:

Bimodal user: Yes No, because.....

2.13.1. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.13.2. CHECK-UP FITTING

Fitting form datalogging & impedances (i02) completed? Yes No

Compliance forms completed? Yes No

Remarks

2.13.3. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest	
Listening	CI			CI		CI			CI	
CI processor	△			△		○			○	
CI program					
HA program	HA turned off									
Level (dB SPL)	75	65	55	65	75	65	55	65		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.13.4. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA off									
N sentences	10	10	10		10		10		10	
Word list nr.	
Order	1		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.13.5. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
CI program	
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.13.6. DATA MANAGEMENT CHECK-UP

Digital data complete and correctly archived on network drive? Yes No

→ If no, describe steps to be taken:

Source documents correctly archived in filing cabinet? Yes No

→ If no, describe steps to be taken:

Remarks

2.13.7. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.13.8. DEVICE DEFICIENCIES

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Were there any device deficiencies? Yes No

Remarks

2.13.9. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Any signs of tinnitus? Yes No

If yes, on what side(s) Left Right

If yes, to what extent (VAS 0-10)? Left: Right:

Any signs of vertigo? Yes No

Any signs of oscillopsia? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.14. Visit F13 (week 20)

Date:

Bimodal user: Yes No, because.....

2.14.1. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.14.2. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Fitting form (i02) completed? Yes No

Particularities relevant for next fitting? No Yes, note on fitting form

Compliance forms completed? Yes No

Remarks

2.14.3. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest			
Listening	CI			CI		CI			CI			
CI processor	△			△		○			○			
CI program							
HA program	HA turned off											
Level (dB SPL)	75	65	55	65	75	65	55	65				
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Remarks

2.14.4. MATRIX IN QUIET

	Practice		Test		Retest		Test		Retest	
Listening	CI		CI		CI		CI		CI	
CI processor	△ / ○		△		△		○		○	
CI program			
HA program	HA turned off									
N sentences	10	10	10		10		10		10	
Word list nr.	
Order	1		

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

Remarks

2.14.5. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI		CI	CI	CI	CI
CI processor	△ / ○		△	△	○	○
HA program	HA turned off					
N sentences	10	10	10	10	10	10
Word list nr.
Order	1	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

2.14.6. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

2.14.7. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.14.8. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.15. Visit F14 (week 26)

Date:

Bimodal user: Yes No, because.....

2.15.1. TONE AUDIOMETRY

	CI		HA	Unaided	
	△	○		L	R
Processor/Ear	△	○	Bimodal fit	L	R
CI program	CI off	CI off	CI off
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.15.2. SPEECH AUDIOMETRY

	Unaided	
	L	R
Ear		
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.15.3. PREFERENCE SCALES

Preference scales (i03) completed? Yes No

2.15.4. FITTING

Program choice after shared decision making: Standard program Natural program

Fitting form (i02) completed? Yes No

Compliance forms completed? Yes No

Consequences of HA compliance measurements, based on calculations (fitting form) and cut-off points (Appendix Compliance):

Study continuation Removed from HA population/bimodal group?

ECAP completed? Yes No

Spare processor taken in and stored? No Yes -> S/N:

Remarks

.....

2.15.5. QUESTIONNAIRES

	Given to subject	To be returned
Date/...../.....	Visit F15
SSQ-12 (I07)	<input type="checkbox"/>	
HUI-3 (I08)	<input type="checkbox"/>	
ICECAP-A (09)	<input type="checkbox"/>	
Sound quality descriptors (I11)	<input type="checkbox"/>	

Remarks

.....

BREAK

2.15.6. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.15.7. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

2.15.8. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

2.16. Visit F15 (week 26)

Date:

Bimodal user: Yes No

2.16.1. SPEECH AUDIOMETRY

	Test			Retest	Test			Retest	Test			Retest
Listening	CI			CI	HA			HA	CIHA			CIHA
CI processor	Preferred			Preferred	CI turned off				Preferred			Preferred
CI program				CI turned off						
HA program	HA turned off				Bimodal fit				Bimodal fit			Bimodal fit
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.16.2. MATRIX IN QUIET

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Preferred		Preferred	Preferred
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.16.3. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA
CI processor	Preferred		Preferred	Preferred	Preferred	Preferred
CI program	
HA program	Off / bimodal		HA turned off		Bimodal fit	Bimodal fit
N sentences	10	10	10	10	10	10
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

Remarks

.....

BREAK

2.16.4. QUESTIONNAIRES

	Returned and checked
Date/...../.....
SSQ-12 (I07)	<input type="checkbox"/>
HUI-3 (I08)	<input type="checkbox"/>
ICECAP-A (09)	<input type="checkbox"/>
Sound quality descriptors (I11)	<input type="checkbox"/>

Remarks

.....

2.16.5. MATRIX IN NOISE SPATIAL

	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI	CIHA	CIHA	CIHA	CIHA
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred
CI program	
HA program	HA turned off				Bimodal fit	Bimodal fit	Bimodal fit	Bimodal fit
N sentences	10	10	10	10	10	10	10	10
Hammerfall Preset
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

BREAK

2.16.6. LISTENING EFFORT

	Practice	Test	Test
Listening	CI / CIHA	CI	CIHA
CI processor	Preferred	Preferred	Preferred
CI program
HA program	Off / bimodal	HA turned off	Bimodal fit
SRT input (in dB SNR)
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.16.7. LOUDNESS SCALING

	Test	Test
Listening	CI	HA
CI processor	Preferred	CI turned off
CI program	CI turned off
HA program	HA turned off	Bimodal fit
N questions	4	4
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.16.8. SMRT

	Test	Retest	Test	Retest
Listening	CI	CI	HA	HA
CI processor	Preferred	Preferred	CI turned off	
CI program		CI turned off	
HA program	HA turned off		Bimodal fit	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

2.16.9. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....

2.16.10. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

.....

2.16.11. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Remarks

.....

General remarks

.....

3. Second phase

3.1. Visit S1 (week 30)

Date:

Bimodal user: Yes No, because.....

3.1.1. PREFERENCE SCALES

Preference scales (i04) completed? Yes No

3.1.2. FITTING

Particularities from previous fitting to be taken into account? No Yes, see fitting form

Fitting form (i02) completed? Yes No

Compliance forms completed? Yes No

Particularities relevant for next fitting? No Yes, note on fitting form

Remarks

3.1.3. QUESTIONNAIRES

	Given to subject	To be returned
Date/...../.....	Visit T1
SSQ-12 (I07)	<input type="checkbox"/>	
HUI-3 (I08)	<input type="checkbox"/>	
ICECAP-A (09)	<input type="checkbox"/>	
Sound quality descriptors (I11)	<input type="checkbox"/>	

Remarks

3.1.4. SPEECH AUDIOMETRY

	Test			Retest	Test			Retest	Test			Retest
Listening	CI			CI	HA			HA	CIHA			CIHA
CI processor	Preferred			Preferred	CI turned off				Preferred			Preferred
CI program				CI turned off						
HA program	HA turned off				Loudness fit				Loudness fit			Loudness fit
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

3.1.5. MATRIX IN QUIET

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Preferred		Preferred	Preferred
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

3.1.6. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA
CI processor	Preferred		Preferred	Preferred	Preferred	Preferred
CI program	
HA program	Off / loudness		HA turned off		Loudness fit	Loudness fit
N sentences	10	10	10	10	10	10
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

Remarks

BREAK

3.1.7. MATRIX IN NOISE SPATIAL

	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI	CIHA	CIHA	CIHA	CIHA
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred
CI program	
HA program	HA turned off				Loudness fit	Loudness fit	Loudness fit	Loudness fit
N sentences	10	10	10	10	10	10	10	10
Hammerfall Preset
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

3.1.8. LISTENING EFFORT

	Practice	Test	Test
Listening	CI / CIHA	CI	CIHA
CI processor	Preferred	Preferred	Preferred
CI program
HA program	Off / Loudness fit	HA turned off	Loudness fit
SRT input (in dB SNR)
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

3.1.9. LOUDNESS SCALING

	Test	Test
Listening	CI	HA
CI processor	Preferred	CI turned off
CI program	CI turned off
HA program	HA turned off	Loudness fit
N questions	4	4
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

3.1.10. DATA MANAGEMENT CHECK-UP

Digital data complete and correctly archived on network drive? Yes No

→ If no, describe steps to be taken:

.....
.....

Source documents correctly archived in filing cabinet? Yes No

→ If no, describe steps to be taken:

.....
.....

Remarks

.....

3.1.11. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....

3.1.12. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

.....

3.1.13. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Any signs of tinnitus? Yes No

If yes, on what side(s) Left Right

If yes, to what extent (VAS 0-10)? Left: Right:

Any signs of vertigo Yes No

Any signs of oscillopsia? Yes No

Remarks

General remarks

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

4. Third phase

4.1. Visit T1 (week 34)

Date:

...../...../.....

Bimodal user:

Yes

No, because.....

4.1.1. TONE AUDIOMETRY

	HA
Program	Loudness fit
Completed?	<input type="checkbox"/>

Remarks

.....

4.1.2. SPEECH AUDIOMETRY

	Test			Retest	Test			Retest	Test			Retest
Listening	CI			CI	HA			HA	CIHA			CIHA
CI processor	Preferred			Preferred	CI turned off				Preferred			Preferred
CI program				CI turned off						
HA program	HA turned off				Loudness fit				Loudness fit			Loudness fit
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

4.1.3. MATRIX IN QUIET

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Preferred		Preferred	Preferred
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

4.1.4. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA
CI processor	Preferred		Preferred	Preferred	Preferred	Preferred
CI program	
HA program	Off / loudness		HA turned off		Loudness fit	Loudness fit
N sentences	10	10	10	10	10	10
Word list nr.
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Remarks

4.1.5. QUESTIONNAIRES

	Returned and checked
Date/...../.....
SSQ-12 (I07)	<input type="checkbox"/>
HUI-3 (I08)	<input type="checkbox"/>
ICECAP-A (09)	<input type="checkbox"/>
Sound quality descriptors (I11)	<input type="checkbox"/>

Remarks

BREAK

4.1.6. MATRIX IN NOISE SPATIAL

	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI	CI	CI	CI	CIHA	CIHA	CIHA	CIHA
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred	Preferred
CI program	
HA program	HA turned off				Loudness fit	Loudness fit	Loudness fit	Loudness fit
N sentences	10	10	10	10	10	10	10	10
Hammerfall Preset
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

4.1.7. LISTENING EFFORT

	Practice	Test	Test
Listening	CI / CIHA	CI	CIHA
CI processor	Preferred	Preferred	Preferred
CI program
HA program	Off / loudness	HA turned off	Loudness fit
SRT input (in dB SNR)
Order

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
------------	--------------------------	--------------------------	--------------------------

Remarks

4.1.8. LOUDNESS SCALING

	Test	Test
Listening	CI	HA
CI processor	Preferred	CI turned off
CI program	CI turned off
HA program	HA turned off	Loudness fit
N questions	4	4
Word list nr
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

4.1.9. SMRT

	Test	Retest
Listening	HA	HA
CI processor	CI turned off	
CI program	CI turned off	
HA program	Loudness fit	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

BREAK

4.1.10. PREFERENCE SCALES

Preference scales (i04 + i05) completed? Yes No

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

4.1.11. FITTING

Particularities from previous fitting to be taken into account? No Yes,

.....

Fitting form (i02) completed? Yes No

Particularities relevant for next fitting? No Yes, describe here and note on CRF's next visit

.....

Remarks

.....

4.1.12. QUESTIONNAIRES

	Given to subject	To be returned
Date/...../.....	Visit T2
SSQ-12 (I07)	<input type="checkbox"/>	
HUI-3 (I08)	<input type="checkbox"/>	
ICECAP-A (09)	<input type="checkbox"/>	
Sound quality descriptors (I11)	<input type="checkbox"/>	

Remarks

.....

4.1.13. SPEECH AUDIOMETRY

	Test		Retest	
Listening	CI		CI	
CI processor	Clinical		Clinical	
CI program			
HA program	HA turned off			
Level (dB SPL)	75	65	55	65
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

4.1.14. MATRIX IN QUIET

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Clinical program		Clinical program	Clinical program
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr.
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

4.1.15. MATRIX IN NOISE

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Clinical program		Clinical program	Clinical program
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

4.1.16. DATA MANAGEMENT CHECK-UP

Digital data complete and correctly archived on network drive? Yes No

→ If no, describe steps to be taken:
.....
.....

Source documents correctly archived in filing cabinet? Yes No

→ If no, describe steps to be taken:
.....
.....

Remarks
.....

4.1.17. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks
.....

4.1.18. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks
.....

4.1.19. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Any signs of tinnitus? Yes No

If yes, on what side(s) Left Right

If yes, to what extent (VAS 0-10)? Left: Right:

Any signs of vertigo? Yes No

Any signs of oscillopsia? Yes No

Remarks
.....

ELEPHANT (METC 18-028) Version: 3.2 Name investigator: _____ Signature: _____

General remarks

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

4.2. Visit T2 (week 52)

Date:

Bimodal user: Yes No, because.....

4.2.1. TONE AUDIOMETRY

	CI	HA	Unaided	
Processor/Ear	Clinical	Clinical	L	R
Program	CI off	CI off	CI off
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

4.2.2. SPEECH AUDIOMETRY

	Test			Retest		Test			Retest		Test		Retest		
Listening	CI			CI		HA			HA		CIHA		CIHA		
CI processor	Clinical			Clinical		CI turned off					Clinical		Clinical		
CI program				
HA program	HA turned off					Clinical fit					Clinical fit			Clinical fit	
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65	75	65	
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Remarks

.....

BREAK

4.2.3. QUESTIONNAIRES

	Returned and checked
Date/...../.....
SSQ-12 (I07)	<input type="checkbox"/>

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

HUI-3 (I08)	<input type="checkbox"/>
ICECAP-A (09)	<input type="checkbox"/>
Sound quality descriptors (I11)	<input type="checkbox"/>

Remarks

4.2.4. MATRIX IN QUIET

	Practice		Test	Retest
Listening	CI		CI	CI
CI processor	Clinical program		Clinical program	Clinical program
CI program	
HA program	HA turned off			
N sentences	10	10	10	10
Word list nr
Order	1		2	3
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

4.2.5. MATRIX IN NOISE

	Practice		Test	Retest	Test	Retest
Listening	CI / CIHA		CI	CI	CIHA	CIHA
CI processor	Clinical		Clinical	Clinical	Clinical	Clinical
CI program	
HA program	Off / clinical		HA turned off		Clinical	Clinical
N sentences	10	10	10	10	10	10
Word list nr
Order
Completed?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test result (SRT in dB SNR)
Mean result (SRT in dB SNR)			

Remarks

4.2.6. LISTENING EFFORT

	Practice	Test	Test
Listening	CI / CIHA	CI	CIHA
CI processor	Clinical program	Clinical program	Clinical program
CI program
HA program	Off / clinical program	HA turned off	Clinical program
SRT input (in dB SNR)
Order
Completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remarks

.....

BREAK

4.2.7. PREFERENCE SCALES

Preference scales (i04 + i06) completed? Yes No

4.2.8. FITTING

Particularities from previous fitting to be taken into account? No Yes,

.....

Fitting form (i02) completed? Yes No

CI research processor given back and stored? Yes No

HA loaner given back and stored? Yes No

Patient informed about HA reimbursement and acted accordingly? Yes No

Remarks

.....

4.2.9. PROTOCOL DEVIATIONS

Were there any protocol deviations? Yes No

Remarks

.....
.....

4.2.10. DATA MANAGEMENT CHECK-UP

Digital data complete and correctly archived on network drive? Yes No

→ If no, describe steps to be taken:

.....
.....

Source documents correctly archived in filing cabinet? Yes No

→ If no, describe steps to be taken:

.....
.....

Remarks

.....

4.2.11. DEVICE DEFICIENCIES

Were there any device deficiencies? Yes No

Remarks

.....

4.2.12. ADVERSE EVENTS

Checked and acted on adverse events? Yes No

Any signs of tinnitus? Yes No

If yes, on what side(s) Left Right

If yes, to what extent (VAS 0-10)? Left: Right:

Any signs of vertigo? Yes No

Any signs of oscillopsia? Yes No

Remarks

.....

General remarks

End of study

Date of termination of participation in the study:

Date:

Did there occur early termination? Yes No

If yes, specify the reason of early termination.

- (Serious) adverse event
- Retraction of informed consent
- Protocol deviation
- Did not conform to inclusion criteria
- No effect of CI
- Discompliance to CI randomization scheme
- Discompliance to other study procedures

.....
.....
.....

INVESTIGATOR STATEMENT

I am confident that the information supplied in this case record form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.

Principal investigator:

Principal investigator's Signature:

Date of signature (DD-MM-YYYY):

(SERIOUS) ADVERSE EVENTS (SA/SAE)

Serious (see *)	Severity	Relationship to study treatment	Action taken regarding study intervention	Outcome of AE
1 = YES 2 = NO	1 = MILD 2 = MODERATE 3 = SEVERE	1 = DEFINITELY related 2 = POSSIBLY related 3 = NOT related	1 = NONE 2 = DISCONTINUED Permanently 3 = DISCONTINUED Temporarily	1 = RESOLVED, no sequel 2 = AE still PRESENT – NOT treated 3 = AE still PRESENT – Treated 4 = RESIDUAL effects present – NOT treated 5 = RESIDUAL effects present – Treated 6 = UNKNOWN

* Criteria for SAE: Any untoward medical occurrence that at any dose (1) results in death, (2) is life-threatening, (3) requires inpatient hospitalisation or prolongation of existing hospitalization, (4) results in persistent or significant disability incapacity or (5) is a congenital anomaly/birth defect.
If serious = YES → complete SAE form!!!

Nr.	Date	Adverse Event	Start date	Stop date	Serious?	Severity	Relationship	Action	Outcome	Initials + Sign
1.										
2.										
3.										
4.										
5.										
6.										
7.										

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

8.										
9.										
10.										
11.										
12.										
13.										
14.										
15.										
16.										
17.										
18.										

PROTOCOL DEVIATIONS

Nr.	Date	Deviation
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

PROTOCOL DEVIATIONS

Nr.	Date	Deviation
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____

CHANGES IN MEDICATION USE

Medication	Start date of use	End date of use	Indication	Subscribed due to (S)AE?

COMPLIANCE

See SOP Compliance for methods and fitting forms for calculations.

CI

In the table below it is shown to what extent subjects can show non-compliance to the CI randomization schedule before consequences take effect.

	F4	F7	F11
Study continuation			
Removed from per protocol population		When 2x >15%	When 2x >15%
Transferred to clinical care	When >40% x 1	When 2x >25% or >40% x 1 or 1x total usage time <360 min/d	When 2x >25% or >40% x 1 or 1x total usage time <360 min/d

The compliance result that is calculated on visit F11, and includes the time window between F7 and F11, counts double since its time window is also double as long as compared to the results calculated on visits F4 and F7.

HA

In the table below it is shown to what extent subjects can show non-compliance before they will be removed from the HA population.

	F7	F14
Study continuation		
No bimodal testing at visit F10	When < 25%	
Removed from HA population		When < 50%

FORMS

Form nr	Contents
i01	Operation Room
i02	Fitting Form
i03	Preference scale for randomization phase
i03	Preference scale for whole study period except randomization phase
i05	Preference scale for bimodal phase
i06	Preference scale for clinical phase
i07	SSQ questionnaire
i08	HUI questionnaire
i09	ICECAP questionnaire
i10	Sound quality questionnaire
i11	CI compliance form
i12	HA compliance form

SUBJECT ID: _____ SEEN BY MONITOR: _____ DATE: ____/____/____