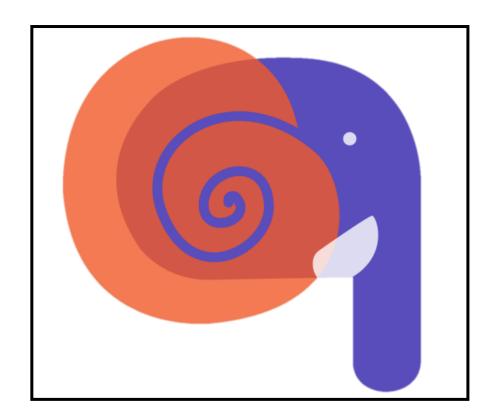
ELEPHANT (METC 18-028) Version: 3.2 Name investigator:	Signature:
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Case Report Form (CRF)

Study number: METC 18-028

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

Study site: Maastricht MUMC +



ELEPHANT-study

CLIDIECT ID.	CEEN BY MACNITOD.	DATE.	, ,	
SUBJECT ID:	ZEEN BY MUDINITURE	DAIF:	/ /	l.
00DJEC1 1D1	3EEN B1 MONTON:		_//	

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

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 O.

• Natural program:

frequency-allocation table is mapped experimentally, following individual natural tonotopy, based on imaging data, programmed on either processor Δ or O.

• 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:/	
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ELEPHANT (METC 18-028) Version: 3.2 Name investigator:S	ignature:	ature:		
INFORMED CONSENT				
Subject ID: E P				
Year of birth:				
Date of subject's written , , ,				
nformed consent:				
nclusion Criteria	Yes	No*		
adult (>18 years of age) and meeting the Dutch standard CI criteria				
proficient speaker of Dutch language				
post-lingual onset of profound deafness (> 4 years of age)				
subject receives an Advanced Bionics HiRes Ultra implant with Midscala electrode a	ind			
an Advanced Bionics processor				
prepared to use study specific hearing aid (Phonak) for the duration of the study (in	1			
case of contralateral HA)				
rehabilitation at MUMC+ for the first year after surgery regarding CI as well as HA				
active participation in trial related procedures such as daily randomization and				
regular testing				
agreed to participate in this part of the study (by informed consent)				
any inclusion criteria are ticked no then the patient is not eligible for the study.				
cclusion Criteria	Yes*	No		
physical or non-physical contraindications for MRI or CT imaging				
additional disabilities that may prevent active participation**				
cochlear or neural abnormalities that could affect outcome measures and/or				
compromise the placement of the electrode array as assessed by the CI surgeon				
active participation in another prospective clinical trial				
pregnancy				
requirement of electric-acoustic activation prior to the first year follow-up				
having received a cochlear implant earlier (e.g. explantation or bilateral implantation	on)			
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, addition		e performed		
vith the Mini-Mental State Examination. Patients will be excluded from the study when the resulting score is lo	wer than 24;			
STER BY MONITOR: DATE:				

ELEPHANT (METC 18-028) Version: 3.2 Name investigator:	Signature:
BASELINE DATA	
LEFT hearing situation	
Etiology of deafness	Unknown/Progressive Other:
Onset of profound deafness (age)	
Current HA-use?	Yes / No
 If yes, since age 	
 If yes, brand and type device 	
 If yes, age current device 	years
 If yes, frequency of usage 	< 5 / 5-10 / > 10 hours/day
RIGHT hearing situation	
Etiology of deafness	Unknown/Progressive Other:
 Onset of profound deafness (age) 	
Current HA-use?	Yes / No
 If yes, since age 	
 If yes, brand and type device 	
 If yes, age current device 	years
 If yes, frequency of usage 	< 5 / 5-10 / > 10 hours/day
Tinnitus Questionnaire (TQ)	
Total score	
• Grade	1/2/3/4
Overall	
Education level	None
	Primary school
	Special education
	LBO/LTS ULO/MBO/MAVO
	HAVO/VWO
	HBO/HEAO/HTS
	Higher science education
Native language	Dutch / other:
 If other, Dutch language level 	Very good / good / average / limited
 Current use of medication 	Yes / No
 If yes, type, dose and indication 	
CLIDIFCT ID. CEEN BY MONITOR.	DATE: / /

ELEPHANT (ME	TC 18-028) Version:	3.2 Name	investigato	r:		_Signature:	
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 Remarks	?		Yes, date:	/		∐ No)	
1.1.2. TONE AUD	DIOMETRY							
	Una	ided	Н	IA	Unaide	ed retest		
Date	/	/	/	/	/	/		
Ear	L	R	L	R	L	R		
Completed?								
Remarks								
1.1.3. SPEECH AU	JDIOMETR	Υ	T					
	Una	ided	Н	IA	Unaide	ed retest		
Date	/	/	/		/	/		
Ear	L	R	L	R	L	R		
Completed?								
Remarks								
1.1.4. REM	ı.a. [¬.,		,				
REM performed	d? [_	Yes, da 	te: <u>/</u>	/		,		
HA refit necess	refit necessary? No Yes, refit on date:/					/		
Retest after ref	it?	No			Yes, re	test on date	::/	
SUBJECT ID:		SEEN BY	MONITOR:			DATE: _		

ELEPHANT (METC 1	L8-028) Version: 3.2	Name investigator:		Sig	gnature:		
				Tone	audio	Speech	audio
				IA .	H.		
			Ear Completed?	L	R	L	R
_			completed:				
Remarks							
1.1.5. EARMOULD							
				, ,		¬	
Adequate earmoul	d available for contra	alateral ear?	Yes, date:	//	L	No, de in rem	
If not, prescription	given?		Yes, date:	//		No	
Remarks							
1.1.6. QUESTIONNA	IRES						
		Daturnad and shae	land				
	Given to subject	Returned and chec	ked				
Date	//	/					
SSQ-12 (I07)							
HUI-3 (I08)							
ICECAP-A (09)							
Remarks							
1 1 7 HADDWARF							
1.1.7. HARDWARE Patient choice for (CL color?	Cilver gray	Chast	en ut			
ratient choice for (TI COIOI !	Silver gray Sand beige	☐ Chest	nut t black			
		Alpine white	□ veive	DIGCK			
SUBJECT ID:	SEEN BY MON	NITOR:	DA	TE:	<u></u>	J	_

ELEPHANT (METC 18-028) Version: 3	.2 Name investigator:	Si	gnature:
Patient choice for HA color?	Silver gray	Chestnut	
	Sand beige	Uelvet black	
	Graphite grey		
Remarks			
4.4.0. DD070001 DEVUATIONS			
1.1.8. PROTOCOL DEVIATIONS			
Were there any protocol deviations?	Y ∈	es No	
Remarks			
<u> </u>			I
General remarks			
SUBJECT ID: SEEN BY M	ONITOR:	DATE:	/ /

ELEPHANT (METC 18-028) Version: 3.2 Name investigator:				Signature:		
1.2. P3: Visit OR						
Date:		/				
1.2.1. IMPLANTATION R	EPORT					
Implantation report (IC	01) completed and signe	ed by surgeon?	Yes	No		
Intraoperative measur	ements performed?		Yes	☐ No		
Particularities that will	influence CI fitting?	No		ribe in remarks and ction 2.1.1 and 2.2.2		
Remarks						
1.2.2. ADVERSE EVENTS						
Checked and acted on Remarks		Ye		lo 		
General remarks						
SUBJECT ID:	SEEN BY MONITOR:		DATE:	/ /		

ELEPHANT (METC 18-028) Ver	sion: 3.2 Name i	nvestigator:	Signature:		
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 TERN	/INATION!	
Scan quality adequate?	Yes	No, new scan p	erformed on/		
Particularities that will influen	ce CI fitting?	□ No □	Yes, describe in remarks ar CRF in section 2.1.1 and 2.2		
Remarks					
1.2.2. FARMOULD					
1.3.3. EARMOULD Adequate earmould available	for contralatora	Lear?			
Adequate earmould available	Ye		cribe steps to be taken befo	ore visit F1:	
1.3.4. PROTOCOL DEVIATIONS					
Were there any protocol devia	ations?	Yes	No		
Remarks					
1.3.5. DEVICE DEFICIENCIES					
Were there any device deficie	ncies?	Yes	☐ No		
Remarks					
1.3.6. ADVERSE EVENTS					
Checked and acted on adverse	e events?	Yes	No		
Remarks					
SUBJECT ID:SEEI	N BY MONITOR:		DATE://		

ELEPHANT (METC 1	8-028) Version: 3.2 Name investigator:	Signature:
General remark	e	
General remark	5	
1		
CUDIFCT ID:	CEEN DV MONITOD.	DATE: / /

ELEPHANT	(METC	18-0	28) Ve	ersion:	3.2 N	ame ir	nvesti	gator:				Sign	nature	:		
2. Firs	t ph	ase)													
2.1. Pre-	fitting	g pre	para	tion												
2.1.1. MAPI	PING															
Mapping p	erform	ned?				Yes, da	ate:	/	/			No				
Electrodes	extrac	ochle	ar?] No			es, el				
Electrodes	folded	lover	in tipî	?] No			es, el				
Impedance	s with	in nor	mal ra	ange (1	1.0 kΩ	≤ valu	ıe ≤ 30).0 kΩ)?							
El number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Y(es)/N(o)																
Number of Remarks	chann	iels m	apped	l < 859	98 Hz (exclud	ding pl)	Note	e on se	ection	2.2.2	ard AN and fir ARLY T	st fitti	ng fori	m!
2.1.2. DAILY												1 —	7			
Randomiza	tion so	chedu	le crea	ated?			_\ 	es, da			/		No			
Any particu	ılaritie	s?					r	No		Yes, d	escribe	e:				
Remarks																······································
2 1 2 TEST	PANDO)N/UZA:	TION -													
Randomiza				ions a	nd wo	ord list	·			/	/] []No			
Any particu	ularitie	s?					r	No		Yes, d	escribe	e:				

SUBJECT ID:_____ SEEN BY MONITOR: __

DATE: ____/__

Remarks				
2.1.4. HARDWAR	Е			
Patient kit ready	y?	Yes, date:/		
Patient processo	or stored safely?	Yes, date:/		
Contralateral ea	rmould available?	Yes, date:/	_No	
	С	I	НА	
Device	Research CI Naida Q70 Δ	Research Naida Q70	Research Naida Link	
Serial number				
Color				
Remarks				
Measurement to	emplate ready in BEPS+?	Yes, date:/		
Natural templat	e ready in BEPS+?	Yes, date:/		
Audiogram read	ly in Phonak Target?	Yes, date:/		
Remarks				

ELEPHANI (MET	C 18-028	S) Versio	n: 3.2 Nam 	ie investigator:	Signature:	
2.2. Visit F1 (wk 0)					
Da	ite:		•••	//		
Bimodal us	ser:		Yes [No, because		
2.2.1. TONE AUDI	OMETRY	,				
	Una	nided]			
Ear	L	R				
Completed?						
Decided to start	with EA	s? [No	☐ Yes → E	ARLY TERMINATION!	
Remarks						
2.2.2. SPEECH AU	DIOMETI	RY				
	Una	aided				
Ear	L	R				
Completed?						
Remarks	<u> </u>					
<u> </u>						
2.2.3. FITTING						
Particularities to	be take	n into ac	count duri	ng fitting:		
from im	pedance	e measur	ements?	☐ No	Yes,	
from EC	AP meas	urement	:s?	☐ No	Yes,	
from CB	CT scan	?		☐ No	Yes,	
Fitting form (i02)) comple	eted?		☐ No	Yes	
Particularities re	levant fo	or next fi	tting?	☐ No	Yes, see fitting form.	
Remarks						
				BREAK		
SUBJECT ID:		_ SEEN B	Y MONITO	R:	DATE:/	<i></i>

Test	2.4. JF LLCII AC	JDIOME	TRY	ersio									
Ci					Datast		Toot		Datast	Toot		Datast	
Cl processor	Listening	+											
Cl program		1	_				$\overline{\bigcirc}$						
HA program Level (dB SPL) 75 65 55 65 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □		+					<u> </u>						
Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ <					110 +	and of							
Remarks Practice Test Retest Test Retest Listening Cl The close of		75	65	55				55	65				
Remarks Additional testing performed with number lists 2.2.5. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl						,				73 03	55		
Additional testing performed with number lists 2.2.5. MATRIX IN QUIET	Completed?												
Additional testing performed with number lists 2.2.5. MATRIX IN QUIET	Remarks												
Practice Test Retest Test Retest Listening CI CI <t< td=""><td><u></u></td><td>esting p</td><td>perfor</td><td>med</td><td>with nur</td><td>nber li</td><td>sts</td><td></td><td></td><td></td><td></td><td></td></t<>	<u></u>	esting p	perfor	med	with nur	nber li	sts						
Practice Test Retest Test Retest Listening CI CI <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>													
Practice Test Retest Test Retest Listening Cl Cl <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>													
Practice Test Retest Test Retest Listening CI CI <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>													
Listening CI	.2.5. MATRIX IN	QUIET											
CI processor ∆ / O ∆ ∆ O O CI program HA turned off N sentences 10 10 10 10 10 Word list nr. Order 1 Completed? □ □ □ □ □ □		Pra	actice		Tes	t	F	Retes	it	Test		Retes	
Cl program	Listening		CI		CI			CI		CI		CI	
HA program N sentences 10 10 10 10 10 10 Word list nr	CI processor	Δ	<u>/ C</u>)	Δ	\		Δ		0		0	
N sentences 10 10 10 10 10 Word list nr.	CI program												
Word list nr. <td< td=""><td>HA program</td><td></td><td></td><td></td><td></td><td></td><td>HA t</td><td>turne</td><td>ed off</td><td></td><td></td><td></td></td<>	HA program						HA t	turne	ed off				
Order 1	N sentences	10	1	0	10			10		10		10	
Completed?													
Remarks	Word list nr.												
Remarks			1			•							
	Order		1			<u>. </u>							
	Order Completed?		1			·							
	Order Completed? Remarks	 e perfo] (too]	ient)						
	Order Completed?	 e perfo		(too]	ient)						
	Order Completed? Remarks	perfo		(too]	ient)						
	Order Completed? Remarks	e perfo		(too]	ient)						
	Order Completed? Remarks	e perfo		(too]	ient)						
	Order Completed? Remarks	e perfo		(too]	ient)						
	Order Completed?	e perfo		(too]	ient)						

SUBJECT ID:_____ SEEN BY MONITOR: _____

_ DATE: ____/_

ELEPHANT (MET	C 18-028	3) Versior	n: 3.2 Name inve	stigator:	Sign	nature:	
2.2.6. MATRIX IN	NOISE						
	Prac	ctice	Test	Retest	Test	Retest	
Listening		CI	CI	CI	CI	CI	
CI processor	Δ	/ O	Δ	Δ	0	0	
CI program							
HA program				HA turned off			
N sentences	10	10	10	10	10	10	
Word list nr.							
Order	-	1					
Completed?							
Remarks							
Not perform	ed, due t	o matrix	in quiet SRT sco	re = < 50%			
2.2.7. PREFERENC	E SCALES						
Preference scale	s (i03) co	ompleted	d?	☐ No			
2.2.8. DATA MAN	AGEMEN	T CHECK-	UP				
Digital data com				etwork drive?	Yes	☐ No	
→ If no, describe						_	
7 II IIO, describe	e steps to	J DE LAKE	111.				
							•
Source documer	nts corre	ctly archi	ved in filing cabi	net?	Yes	☐ No	
→ If no, describe	e steps to	o be take	n:				
	-						
		•••••					•
							•
Remarks							
2.2.9. PROTOCOL							
Were there any	protocol	deviatio	ns?	Yes	☐ No		
Remarks							
		-				·	
SUBJECT ID:		SEEN B'	Y MONITOR:		DATE:	/ /	

			Signature:	
2.10. DEVICE DEFICIENCI	ES			
ere there any device d	eficiencies?	Yes	No	
2.11. ADVERSE EVENTS				
necked and acted on a	dverse events?	Yes Yes	☐ No	
y signs of tinnitus?		Yes	☐ No	
yes, on what side(s)		Left	Right	
yes, to what extent (V	AS 0-10)?	Left:	Right:	
ny signs of vertigo?		Yes	No	
ny signs of oscillopsia?		Yes	No	
emarks				
JBJECT ID:	SEEN BY MONITOR:		DATE: / /	

articularities from previous fitting to be taken into account? No Yes, see fitting form litting form (i02) completed? Yes No larticularities relevant for next fitting? No Yes, note on fitting form loompliance forms completed? Yes No loompliance forms completed? Yes No loompliance forms completed? Yes No loompliance forms seemarks	ELEPHANT (METO	2 18-028) Version	n: 3.2 Nam	e investiga	ator:		Signature:	
Bimodal user:	2.3. Visit F2 (\	week 1)						
3.1. PREFERENCE SCALES reference scales (i03) completed?	Da	nte:		/	/			
reference scales (i03) completed?	Bimodal us	er:	Yes [No, beca	ause			
articularities from previous fitting to be taken into account? No Yes, see fitting form itting form (i02) completed? Yes No Yes, note on fitting form compliance forms completed? Yes No CAP completed	2.3.1. PREFERENCE	SCALES						
articularities from previous fitting to be taken into account? No Yes, see fitting form litting form (i02) completed? Yes No larticularities relevant for next fitting? No Yes, note on fitting form loompliance forms completed? Yes No loompliance forms completed? Yes No loompliance forms completed? Yes No loompliance forms seemarks	Preference scales	(i03) completed	l?	Yes	□ N	0		
itting form (i02) completed?	2.3.2. FITTING							
articularities relevant for next fitting? No Yes, note on fitting form compliance forms completed? Yes No CAP completed? Yes No cemarks No Yes No	Particularities fro	m previous fittin	g to be tal	ken into ac	ccount?	☐ No	Yes, see fitting form	
CAP completed?	Fitting form (i02)	completed?		Yes	□ N	0		
A.3.3. SPEECH THERAPY articularities from speech therapy to be taken into account? No Yes, note here stemarks SPEECH AUDIOMETRY	Particularities rel	evant for next fit	ting?	No	Y	es, not	te on fitting form	
A.3. SPEECH THERAPY Tarticularities from speech therapy to be taken into account? No Yes, note here SEMETAR BREAK 3.4. SPEECH AUDIOMETRY Test Retest Test Retest Listening Cl Cl Cl Cl Cl processor A A O O Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? Level (dB SPL) Test Retest	Compliance form	s completed?		Yes	□ N	О		
### Particularities from speech therapy to be taken into account? ☐ No ☐ Yes, note here #### Particularities from speech therapy to be taken into account? ☐ No ☐ Yes, note here ##################################	ECAP completed?)		Yes	□ N	О		
BREAK 3.4. SPEECH AUDIOMETRY Test Retest Test Retest Listening Cl Cl Cl Cl Cl processor \(\triangle \t								٦
Test	Remarks			••••••	••••••			
Test Retest Test Retest Listening CI CI CI CI CI processor △ △ O O CI program HA program HA turned off Level (dB SPL) 75 65 55 65 55 65 Completed? □ □ □ □ □ □ □ Additional testing performed with number lists				BRE	AK			
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? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	2.3.4. SPEECH AUD	DIOMETRY						
Cl processor △ △ O O Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 55 65 Completed? □ □ □ □ □ □ □ Bemarks Additional testing performed with number lists		Test	Retest	Test	F	Retest		
Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed?		CI	CI	CI		CI	_	
HA program	-	Δ		U		<u>U</u>		
Level (dB SPL) 75 65 55 65 75 65 55 65 Completed?								
Completed?		75 65 55			55	65	-	
Additional testing performed with number lists							-	
	Remarks							
UBJECT ID: SEEN BY MONITOR: DATE: / /	Additional tes	ting performed	with numb	er lists				
	SUBJECT ID:	SEEN BY	/ MONITO	R:			DATE:/	7

		8) versioi	n: 3.2 Name inve	estigator:	Sig	nature:
2.3.5. MATRIX IN	QUIET					
	Prac	tice	Test	Retest	Test	Retest
Listening	С		CI	CI	CI	CI
CI processor	Δ /	0	Δ	Δ	0	0
CI program						
HA program				HA turned off		
N sentences	10	10	10	10	10	10
Word list nr.						
Order	1				•••••	
Completed?						
Remarks						
2.3.6. MATRIX IN	NOISE					
	Pra	ctice	Test	Retest	Test	Retest
Listening		CI	CI	CI	CI	CI
CI processor	Δ	<u>/ O</u>	Δ	Δ	0	0
CI program						
HA program				HA turned off		
N sentences	10	10	10	10	10	10
Word list nr.						
Order		1				
Completed?						
Remarks						
Not perform	ed, due	to matrix	in quiet SRT sco	ore = < 50%		
2.3.7. PROTOCOL	DEVIATI	ONS				
Were there any			ins?	Yes	□No	
	٥.٥٥٥٥	. acviatio			140	
Remarks						
SUBJECT ID:		CEENID	Y MONITOR:		DATE:	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investi	gator:	Signature:	
2.3.8. DEVICE DEFICIENCII	ES			
Were there any device of		Yes	□No	
Remarks				
2.3.9. ADVERSE EVENTS				
Checked and acted on a	dverse events?	Yes	No	
Remarks				
General remarks				
1				l
SUBJECT ID:	SEEN BY MONITOR:		DΔTF· / /	=

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE:/

ELEPHANT (METC	18-028) Ve	ersion: 3.	2 Name inves	tigator:	Signature:
2.4. Visit F3 (v	veek 2)				
D	ate:		/	//	
Bimodal u	ıser:	Yes	☐ No, k	oecause	
2.4.1. TONE AUDIC	METRY				
Processor Cl program Completed? Remarks	CI	0	HA Bimodal fit CI off		
2.4.2. REM					
Test completed? Changes made to Remarks	HA setting:	s as a res	ult of REM?	☐ No ☐ No	☐ Yes ☐ Yes, see fitting form
2.4.3. PREFERENCE	SCALES				
Preference scales	(i03) comp	leted?	Yes	☐ No	
2.4.4. FITTING					
Particularities fro Fitting form (i02)				o account? No	Yes, see fitting form
Particularities relo Compliance form Remarks			? No	Yes, note on	fitting form
Remarks			-		
2.4.5. SPEECH THE	RAPY				
Particularities froRemarks	m speech tl	herapy to	be taken into	o account? No	Yes, note here
			В	REAK	
SUBJECT ID:	SE	EN BY MO	ONITOR:		DATE:/

ELE	PHANT (ME	ΓC 18-0)28) \	/ersic	n: 3.2 Na	ame ir	ivesti	gator	·		Sig	nature: _		
2.4.	.6. QUESTION	NAIRES												
					Given t	o sub	ject		Го be turned					
	D	ate			/.	/			:a:+ F4					
Sc	ound quality	descrip	otors	(111)				V	isit F4					
Rer	marks													
2.4.	.7. SPEECH AL	JDIOME	TRY											
		-	Test		Retest		Test		Retest		Test	Retest	7	
	Listening		CI		CI		CI		CI		НА	НА		
	CI		Δ		Δ		O		0		CI turned	off		
(CI program										CI turned	off		
H	HA program				HA tur	ned of	ff				Bimodal	fit		
	Level (dB	75	65	55	65	75	65	55	65	75	65 55	65		
C	Completed?													
Re	emarks							ı			\ 			
L	Additional	testing	perf	orme	d with n	umbei	r lists							
2.4.	.8. MATRIX IN	I QUIET												
	ſ	Des	action		Ta	~+		Dot	oct T	-		Dot	oct	
	Listening	Pra	ectice CI	=	Te:			Ret		ļ	est CI	Ret C		
	processor	Λ	, (<u> </u>				^			\bigcap		<u> </u>	
	l program		<u>/ C</u>	,		7			7		<u> </u>			
	A program						Н	Δ turr	ned off					
	sentences	10	1	10	10)		10			10	1	0	
	ord list nr.													
	Order		1		****			***	🕇					
Co	ompleted?		Ī							,				
Rer	marks											1		
SUI	BJECT ID:		S	EEN E	BY MONI	TOR:				D/	ATE:		'	

LEPHANT (MET	C 18-028) V	/ersion:	3.2 Name inve	estigator:	r:Signature:					
.4.9. MATRIX IN	NOISE									
	Practio	ce	Test	Retest	Test	Retest				
Listening	CI		CI	CI	CI	CI				
CI processor	Δ / (Δ/Ο Δ		Δ	O	0				
CI program										
HA program				HA turned off						
N sentences	10	10	10	10	10	10				
Word list nr.										
Order	1									
Completed?										
2.4.10. PROTOCO	L DEVIATION	NS								
Were there any Remarks										
2.4.11. DEVICE DE		ciencies	?	Yes	☐ No					
2.4.12. ADVERSE I Checked and act Remarks		rse ever	nts?	Yes	□ No					
General rema	arks									
SUBJECT ID:	S	EEN BY I	MONITOR:		DATE:					

ELEPHANT (METC 18-0	28) Version: 3.2 Name investigator:	Si _§	gnature:
SUBJECT ID:	SEEN BY MONITOR:	DATE:	

ELEPHANT (ME	TC 18-028) Versi	on: 3.2 N	ame investiga	tor:	Sig	nature:	
2.5. Visit F4	(week 3)						
	Date:		/	/			
Bimoda	aluser:	Yes	□ No. beca	use			
2.5.1. PREFEREN							
	es (i03) completo	ed?	Yes	□No			
2.5.2. FITTING		-				-	
Particularities f	rom previous fitt	ing to be	taken into acc	count?	No Yes, s	ee fitting fo	orm
Fitting form (i02	2) completed?		Yes	No			
Particularities r	elevant for next	fitting?	☐ No	Yes, note	e on fitting form		
Compliance for	ms completed?		Yes	No			
Consequences	of CI compliance	measure	ements, based	on calculat	ions (fitting form	n) and cut-	off points
(Appendix Com							
☐ Stud	dy continuation		☐ Early termi	nation and	transfer to clinic	cal care	
_	a, communication					a. ca. c	
Remarks							
2.5.3. SPEECH TH	IERAPY						
Particularities f	rom speech ther	apy to be	e taken into ac	count?	No Yes, n	ote here	
Damania		•••••					
Remarks							
2.5.4. SPEECH AU	JDIOMETRY						
	Test	Retest	Test	Retest	Test	Retest	
Listening	CI	CI	CI	CI	HA	НА	
CI processor	Δ	Δ	O	O	CI turned		
CI program					CI turned		
HA program	75 65 55		ned off	- (-	Bimodal		
Level (dB SPL)	75 65 55	65	75 65 5	5 65	75 65 55	65	
SUBJECT ID:	SEEN	BY MON	ITOR:		DATE:		

ELEPHANT (ME	TC 18	-028)	CIHA										
Completed?													
		Test		Potest		Toct		Potost					
Listening		CIHA											
CI processor		Δ		_									
CI program		_ 											
HA program				Bimo	dal fit								
Level (dB SPL)	55	65	75	65	55	65	75	65					
Completed?													
Remarks											 1		
<u> </u>											 		
2.5.5. MATRIX II	N QUIE	ΞT											
	P	ractio	ce	Te	est		Re	test		Test	Re	test	
Listening		CI										CI	
CI processor	L	2 / (<u> </u>	L	7			7		U		<u>J</u>	
CI program							⊔ ∧ +	nod off			 		
HA program N sentences	10	,	10	1	0	т				10	,	10	
Word list nr.													
	••••		•••••	•••	•••		•••			•••••	•	•••	
Order		1			•••		•••			•••••		••••	
Completed?]											
Remarks											 		
l											 		
						В	REAL	(
SUBJECT ID:			SFFN	BY MON	ITOR:				[DATE:	/	/	

ELEPHANT (ME	IC 18-	028) V	rersion	: 3.2 Nam	ie investiga	tor:		Sign	nature:	
2.5.6. QUESTION	NAIDE	<u> </u>	_	_			_			
2.5.0. QUESTION	IVAIRE	3				_				
				Returned	and checke	ed?				
D	ate				/					
Sound quality	doceri	ntorc	(111)							
Sound quality	uescri	ptors	(111)							
Remarks										
2.5.7. MATRIX IN	NOISE									
	Prac	ctice	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI /	CIHA	CI	CI	CIHA	CIHA	CI	CI	CIHA	CIHA
CI processor	Δ	0	Δ	Δ	Δ	Δ	0	0	0	0
CI program	1									
HA program		bim		A off	Bimodal	Bimodal		off	Bimodal	Bimodal
N sentences	10	10	10	10	10	10	10	10	10	10
Word list nr.										
Order										
Completed?										
Test result (SRT in dB SNR)										
Mean result (SRT in dB SNR)		••••					••	••••		
Remarks						. 500/				
Not perform	ied, di	ue to r	natrix i	in quiet S	RT score = <	< 50%				
2.5.8. PROTOCOI	DEVI	TIONS								
				•				٦		
Were there any	proto	col de	viation	IS?		Yes	L	No		
Remarks										
SUBJECT ID:		SI	EEN BY	MONITO	R:		DA	ТЕ:	/ /	

ELEPHANT (METC 18-0	028) Version: 3.2 Name invest	igator:	Signature:	
2.5.9. DEVICE DEFICIENC	CIES			
Were there any device	e deficiencies?	Yes	☐ No	
Remarks				
2.5.10. ADVERSE EVENT	S			
Checked and acted on	adverse events?	Yes	☐ No	
Remarks				
General remarks				
General Temarks				
SUBJECT ID:	SEEN BY MONITOR:		DATE: / /	

ELEPHANT (METC	2 18-028) Versi	on: 3.2 Na	ime investigatoi	r:	Signature:			
2.6. Visit F5 (v	week 4)							
С	Date:		/	/				
Bimodal	user: [Yes	No, becaus	e				
2.6.1. SPEECH THE	RAPY							
Particularities fro	m speech ther	apy to be	taken into acco	unt? 🗌 No	Yes, note here			
Remarks								
2.6.2. PREFERENCE	SCALES							
Preference scales	(i03) complet	ed?	Yes	No				
2.6.3. CHECK-UP FI	TTING							
Preference scale	es (i03) comple	ted?	Yes	No				
Fitting form data	alogging & imp	edances (i02) completed	? 🗌 Yes	□No			
Compliance form	ns completed?	•	Yes	No				
Remarks								
2.6.4. SPEECH AUD	DIOMETRY							
	Test	Retest	Test	Retest				
Listening	CI	CI	CI	CI				
CI processor	Δ	Δ	0	0				
CI program								
HA program		HA tur	ned off					
Level (dB SPL)	75 65 55	65	75 65 55	65				
Completed?								
Remarks	I							
SUBJECT ID:	SEEN	BY MONIT	ΓOR:		DATE:/			

ELEPHANI (ME	TC 18-02	(8) Versi	on: 3.2 Name inv	estigator:	Sig	nature:	
2.6.5. MATRIX IN	I QUIET						
Listening		ctice	Test	Retest CI	Test	Retest CI	
Cl processor	Δ		CI	Δ	CI	0	
CI program	,						
HA program				 HA off	•••		
N sentences	10	10	10	10	10	10	
Word list nr.							
Order	-	1	2	3	4	5	
Completed?							
Remarks							
2.6.6. MATRIX IN	N NOISE						
2.0.0. WATRIX II			T	Datasi	T	D. J. J.	
Listening		ctice Cl	Test CI	Retest CI	Test CI	Retest CI	
Cl processor		/ O	Δ	Δ	0	O	
Cl program							
HA program				HA off			
N sentences	10	10	10	10	10	10	
Word list nr.							
Order	:	1	2	3	4	5	
Completed?							
Test result (SRT in dB SNR)							
Mean result (SRT in dB SNR)							
Remarks							
Not perforn	ned, due	to matri	ix in quiet SRT sc	ore = < 50%			
				BREAK			
SUBJECT ID:		SEEN	BY MONITOR:		DATE:		

ELEPHANT (METC	18-028) Version:	3.2 Name invest	igator:	Signatui	re:
2.6.7. LISTENING E	FFORT				
	Practice	Test	Test	Test	Test
Listening	CI	CI	CI	CIHA	CIHA
CI processor	Δ/Ο	Δ	0	Δ	0
CI program					
HA program	Off / bimodal		IA off	Bimodal fit	Bimodal fit
N	1	5	5	5	5
SRT input (in dB			<u> </u>	3	<u> </u>
SNR)	••••••	••••••		••••••	
31111)					
Order					
Completed?					
Remarks					
2 6 2 1 QUIDNESS 6	CALINIC				
2.6.8. LOUDNESS S	CALING				
	Test	Test	Test		
Listening	CI	CI	НА		
CI processor	Δ	0			
CI program			CI off		
HA program	HA of		Bimodal fit		
N frequencies	4	4	4		
	7	-	-		
Order					
0 1 12					
Completed?					
Remarks					
2.6.9. SMRT					
	Toot	Datast	Toot	Datast	7
Lintanio	Test	Retest	Test	Retest	1
Listening	CI A	CI ^	CI	CI	_
CI processor	Δ	Δ	U	U	_
CI program					
HA program		HA tu	irned off		4
Completed?					
Remarks					
SUBJECT ID:	SEEN BY N	VIONITOR:		DATE:/	/

ELEPHANT (METC 18-0	028) Version: 3.2 Name inves	tigator:	Signature:	
2.6.10. PROTOCOL DEV	IATIONS			
Were there any proto	col deviations?	Yes	No	
Remarks				
2.6.11. DEVICE DEFICIEN	NCIES			
Were there any device	e deficiencies?	Yes	No	
Remarks				
2 C 12 ADVEDSE EVENT	rc			
2.6.12. ADVERSE EVENT		Yes	□ No	
Remarks	i duverse events:			
General remarks				
SUBJECT ID:	SEEN BY MONITOR:		DATE://	

ELEPHANI (MEI	C 18-0	028) \	/ersio	n: 3.2 Na	me ir	ıvesti	gator:		Signature:
2.7. Visit F6 (wee	k 5)							
	Date:					/		/	
Rimodal	Pate:								
] 103	''	10, 50	cause		
			thera	ny to be	taken	into	accou	nt? \square N	o Nes note here
Remarks									
272 DEFERENC	E SCA	IES							
			plete	d?	Yes			∃ No	
			Бістс	<u>. </u>					
			imped	dances (i0)2) co	mplet	ed?	Yes	□No
_		_			_				_
Remarks									
						BR	EAK		
2.7.4. SPEECH AU	DIOM	ETRY							
		CI		_		CI		CI	
		Δ		Δ		O		O	
				∐ Λ +r	nod o	ff			
Level (dB SPL)	75	65	55	I			55	65	
Completed?									
Particularities from speech therapy to be taken into account? No Yes, note here No. No. Yes, note here									
CURIECTIO		c	FEN B	V MONIT	-OR•				DATE: / /

ELEPHANT (MET	C 18-028	8) Versio	n: 3.2 Name inve	estigator:	Się	gnature:	
2.7.5. MATRIX IN	QUIET						
	Pra	ctice	Test	Retest	Test	Retest	
Listening	(CI	CI	CI	CI	CI	
CI processor	Δ/Ο		Δ	Δ	0	0	
CI program			•				
HA program				HA turned of	f		
N sentences	10	10	10	10	10	10	
Word list nr.							
Order		1	2	3	4	5	
Completed?							
Remarks							<u> </u>
2.7.6. MATRIX IN	NOISE						
	Prac	tice	Test	Retest	Test	Retest	
Listening	С	ı	CI	CI	CI	CI	
CI processor	Δ /	/ O \ \ \ \ \ \ \		Δ	0	0	
CI program							
HA program				HA turned off			
N sentences	10	10	10	10	10	10	
Word list nr.							
Order	1						
Completed?							
Remarks	<u></u>						
	ied, due	to matrix	in quiet SRT sco	ore = < 50%			
2.7.7. PROTOCOL	. DEVIATI	ONS					
Were there any			ons?	Yes	☐ No		
Remarks							
SUBJECT ID:		CEENI D	V MONITOR:		DΔTF·		

ELEPHANT (METC 18-028) Version: 3.2 Name investigator:			Signature:	
2.7.8. DEVICE DEFICIENC	TIFS			
Were there any device	e deficiencies?	Yes	☐ No	
Remarks				
2.7.9. ADVERSE EVENTS				
Checked and acted on	adverse events?	Yes	□No	
checked and deted on	daverse events:			
Remarks				
General remarks				
,				
l				
SUBJECT ID:	SEEN BY MONITOR:		DATE: /	/

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator: _	Signature:
SUBJECT ID:	SEEN BY MONITOR:	DATE:/

2.8. Visit F7 (week 6) Date:	
Bimodal user: Yes No, because	
CI Program △ O CI program Completed? □ Remarks	
CI Program △ O CI program Completed? □ Remarks	
Program △ ○ CI program Completed? □ Remarks	
CI program Completed? Remarks	
Completed? Remarks	
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	e fitting form
Particularities relevant for next fitting? No Yes, note on fitting form	
Fitting form (i02) completed?	
Compliance forms completed?	and cut-off points
(Appendix Compliance):	
Study continuation Removed from CI per protocol population	on
Early terminated and transferred to clinical care	
Consequences of HA compliance measurements, based on calculations (fitting form)) and cut-off points
(Appendix Compliance):	
\square Study continuation \square No bimodal testing at F10 \rightarrow Check 'No	bimodal user at 2.10'
Remarks	
<u> </u>	
SUBJECT ID: SEEN BY MONITOR: DATE:/	

	METC 18-028) Version: 3.2 Name investigator:Signature:									
.8.4. SPEECH TH	ERAPY	,								
articularities fr	om sp	eech	thera	py to be	taken ir	nto accou	nt? 🔲 N	o 🗌 Yes, r	note here	
Remarks										
					F	BREAK				
.8.5. SPEECH AL	IDIOMI	FTRV			•					
.0.3. 31 EEE11 AC										
Listening		Test CI		Retest CI		est Cl	Retest CI			
CI processor		Λ		Λ		$\mathbf{\hat{O}}$	\bigcap			
CI program										
HA program				HA tur	ned off					
Level (dB SPL)	75	65	55	65		65 55	65			
Completed?										
emarks										
2.8.6 MATRIX IN QUIET										
.8.6. MATRIX IN	QUIET	-								
.8.6. MATRIX IN		ractio	ce	Te	est	Ret	est	Test	Retest]
Listening			ce	Te		Ret		Test Cl	Retest]
Listening CI processor		ractio	ce O							
Listening CI processor CI program		ractio			7		7	CI		-
Listening CI processor CI program HA program	P	CI /	0				ned off	CI O	CI O	-
Listening CI processor CI program HA program N sentences		CI /					ned off	CI	CI	-
Listening CI processor CI program HA program N sentences Word list nr.	P	CI /	0				ned off	CI O	CI O	
Listening CI processor CI program HA program N sentences Word list nr. Order	10	CI /	10	1		HA tur	ned off	CI O	CI O 	
Listening CI processor CI program HA program N sentences Word list nr.	10	CI /	10	1		HA tur	ned off	CI O 	10 	

ELEPHANT (MET	C 18-028	3) Versior	i: 3.2 Name inve	estigator:	Sig	nature:	
2.8.7. MATRIX IN	NOISE						
	Prac	ctice	Test	Retest	Test	Retest	
Listening		CI	CI	CI	Cl	CI	
CI processor	Δ/Ο		Δ	Λ	0	0	
CI program							
HA program			HA turned off				
N sentences	10	10	10	10	10	10	
Word list nr.							
Order		1					
Completed?							
Remarks				1			
2.8.8. PROTOCOL	DEVIATIO	ONS					
Were there any			ns?	Yes	□No		
Remarks							
2.8.9. DEVICE DEF	ICIENCIE	S					
Were there any	device d	eficiencie	es?	Yes	☐ No		
Remarks							
2.8.10. ADVERSE	EVENTS						
Checked and act	ed on ac	dverse ev	ents?	Yes	☐ No		
Remarks							
General rema	arks						
SUBJECT ID:		_ SEEN B\	MONITOR:		DATE:	JJ	_

ELEPHANT (METC 18-028	8) Version: 3.2 Name investigator:	Signature:	_
SUBJECT ID:	SEEN BY MONITOR:	DATE:/	

0 V!=!(FC	_		_	·	· <u>-</u>		_		_	_		_	_	_	
9. Visit F8	(weel	k 7)													
	Date:	:				/		/							
Bimoda	ıl user:	:] Yes		lo, be	cause								
.9.1. SPEECH TH	IERAPY	7													
articularities fr	om sp	eech	thera	py to be	taken	into a	accou	nt? 🔲 N	lo	Ye	s, note	here			
emarks															
.9.2. PREFEREN	CE SCA	LES													
reference scale	es (i03) com	plete	d? [Yes	;		No							
.9.3. CHECK-UP	FITTIN	G													
itting form d-t				Janaan /:)3) co	mnlat	ed? [Yes				lo			
itting form dat	aloggi	ng & i	mped	iances (ii	02) (0	ilibie					Ш'	NO			
ompliance fori				_	Yes			No			'	NO			
_				_	_			_			' <u>ٺ</u> 				
ompliance for				_	_			_							
ompliance for				_	_		EAK	_							
ompliance for	ms cor	mpleto		_	_			_							
ompliance form	ms cor	mpleto		_	_			_							
ompliance form Remarks 9.4. SPEECH AL	ms cor	mpleto		Retest CI	_	BR		No							
.9.4. SPEECH AU Listening CI processor	ms cor	ETRY		Retest	_	BR		No							
.9.4. SPEECH AL Listening CI processor CI program	ms cor	ETRY Test CI		Retest CI	Yes	BR Test CI		No							
emarks P.4. SPEECH AU Listening CI processor CI program HA program	JDIOM	ETRY Test Cl	ed?	Retest CI A	Yes	BR Test CI O	EAK	Retest CI							
Personal Compliance for the Remarks 9.4. SPEECH AL Listening CI processor CI program HA program Level (dB SPL)	ms cor	ETRY Test CI	ed?	Retest CI	Yes	BR Test CI	EAK	No							
emarks P.4. SPEECH AU Listening CI processor CI program HA program	JDIOM	ETRY Test Cl	ed?	Retest CI A	Yes	BR Test CI O	EAK	Retest CI							

ELLI IIANI (IVIET	C 10-020	y version	i. 3.2 Ivallie liive	estigator:		nature:
2.9.5. MATRIX IN	QUIET					
	Prac	tice	Test	Retest	Test	Retest
Listening	C		CI	CI	CI	CI
CI processor	Δ/Ο		Δ	Δ	0	0
CI program						
HA program				HA off		
N sentences	10	10	10	10	10	10
Word list nr.						
Order	1	L				
Completed?						
Remarks	<u> </u>		<u> </u>			
2.9.6. MATRIX IN	NOISE					
	Prac	tice	Test	Retest	Test	Retest
Listening	C	:I	CI	CI	CI	CI
CI processor	Δ	O	Δ	Δ	0	0
CI program						
HA program				HA turned off		
N sentences	10	10	10	10	10	10
Word list nr.						
Order	1	_				
Completed?						
Remarks						
2.9.7. PROTOCOL	DEVIATIO	ONS				
Were there any	protocol	deviatio	 ns?	Yes	☐ No	
Remarks						
		48 888 88 888 88 88				
SUBJECT ID:		SEEN B	Y MONITOR:		DATE:	1 1

ELEPHANT (METC 18-028)) Version: 3.2 Name investig	;ator:	Signature:	
2.9.8. ADVERSE EVENTS				
Checked and acted on adv	verse events?	Yes	No	
Remarks				
General remarks				
				ļ
				ļ
SUBJECT ID:	SEEN BY MONITOR:		DATE:/	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE:/

ELEPHANT (MET			_					
2.10. Visit F9	(week	k 8)						
ı	Date:				/	/		
Bimodal	user:		Yes	□ No	o, because			
2.10.1. SPEECH TH	IERAPY							
Particularities fro	om spee	ech ther	apy to be t	taken i	nto accou	nt? 🗌 No	Yes, note here	
Remarks								
2.10.2. PREFEREN	CE SCAL	.ES						
Preference scales	s (i03) c	complete	ed?	Yes		No		
2.10.3. CHECK-UP	FITTING	G						
Fitting form data	logging	& imne	dances (i0	2) com	npleted?[Yes	No	
Titting form data	666	, a iiipc						
				Yes		No		
Compliance form ECAP measured?	ns comp			Yes		No Yes	□No	
Compliance form	ns comp			Yes		_	□No	
Compliance form ECAP measured?	ns comp			Yes		_	□ No	
Compliance form ECAP measured?	ns comp	oleted?		Yes		_	□ No	
Compliance form ECAP measured? Remarks	JDIOME	oleted?	Retest		Test	_	□ No	
Compliance form ECAP measured? Remarks	JDIOME	oleted?			Test	Yes	□ No	
Compliance form ECAP measured? Remarks 2.10.4. SPEECH AL	JDIOME	etrry	Retest			Yes	□ No	
Compliance form ECAP measured? Remarks 2.10.4. SPEECH AL	JDIOME	etrry CI	Retest			Yes	□ No	
Compliance form ECAP measured? Remarks 2.10.4. SPEECH AL Listening CI processor	JDIOME	etry Test CI	Retest		CI	Yes	□ No	
Compliance form ECAP measured? Remarks 2.10.4. SPEECH AL Listening CI processor CI program	JDIOME	etry Test CI	Retest CI		CI	Yes	□ No	
Compliance form ECAP measured? Remarks 2.10.4. SPEECH AL Listening CI processor CI program HA program	JDIOME	est CI	Retest CI A	ned of	CI	Retest Cl O	□ No	

ELEPHANT (MET	C 18-028	3) Versioi	n: 3.2 Name inve	stigator:	Sign	nature:	
2.10.5. MATRIX IN	I QUIET						
	Prac	ctice	Test	Retest	Test	Retest	7
Listening		CI	CI	CI	CI	CI	1
CI processor	Δ	/ O	Δ	Δ	0	0	
CI program		••••		•••			
HA program				HA off			
N sentences	10	10	10	10	10	10	
Word list nr.							
Order	:	1					
Completed?							
Remarks		<u> </u>	<u> </u>	<u> </u>		<u> </u>	
2.10.6. MATRIX IN	NOISE						
	Prac	ctice	Test	Retest	Test	Retest	
Listening		Cl	CI	CI	CI	CI	
CI processor		7	Δ	Δ	0	0	
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?							
Remarks	l .	ı					
SUBJECT ID:		SEEN B	Y MONITOR:		DATE:		

ELEPHANT (METC 18-02	8) Version: 3.2 Name invest	igator:	Signature:	
2.10.7. PROTOCOL DEVIA	TIONS			
Were there any protoco	ol deviations?	Yes	No	
Remarks				
2.10.8. DEVICE DEFICIENC				
Were there any device of Remarks	deficiencies?	Yes	∐ No	
2.10.9. ADVERSE EVENTS				
Checked and acted on a	dverse events?	Yes	☐ No	
Remarks				
General remarks				
SUBJECT ID:	SEEN BY MONITOR:		DATE://	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:		Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE: _	/

2.11. Visit F10	(week	(10)										
Da	ate:				/	/						
			٦.,									
Bimodal u	ser:		_ Yes	No	, beca	iuse						
2.11.1. SPEECH THE	RAPY											
Particularities from	1 speecl	h thera	apy to	be taken i	nto ac	count? [☐ No	Y	es, not	e here	9	
					•••••		•••••					
Remarks												
2.11.2. PREFERENCE	SCALES	;										
Preference scales ((i03) coı	mplete	ed?	Yes		☐ No	0					
.11.3. CHECK-UP FI	TTING											
itting form datalo	gging 8	k impe	dance	es (i02) com	pleted	d? 🗌 Y	'es			No		
Compliance forms	comple	eted?		Yes		☐ No	0					
Compliance forms Remarks	comple	eted?		Yes		☐ No	0					
	comple	eted?		Yes		□ No	0					
Remarks		eted?		Yes		□ No						
Remarks		eted?	Giv		ect To	No						
Remarks		eted?	Give	Yes	ect To							
Remarks	AIRES	eted?										
Remarks 2.11.4. QUESTIONN Date	AIRES			en to subje			urned					
Remarks 2.11.4. QUESTIONNA	AIRES			en to subje		o be retu	urned					
Pate Sound quality des	AIRES			en to subje		o be retu	urned					
Remarks 2.11.4. QUESTIONN Date Sound quality des Remarks	AIRES	s (I11)		en to subje		o be retu	urned					
2.11.4. QUESTIONNA	AIRES	s (I11)		en to subje		o be retu	urned					
Pate Sound quality des Remarks 2.11.5. SPEECH AUD	AIRES	s (I11)		en to subje		o be retu Visit F	urned	Retest		Test		Retest
Pate 2.11.4. QUESTIONN Date Sound quality des Remarks 2.11.5. SPEECH AUD Listening	AIRES	s (I11)		en to subje		o be retu	urned	Retest		НА	urnad	НА
Remarks 2.11.4. QUESTIONNA Date Sound quality des Remarks 2.11.5. SPEECH AUD Listening CI processor	AIRES	s (I11)		en to subje		o be retu Visit F	urned			HA CI tu	urned (HA
Date Sound quality des Remarks 2.11.5. SPEECH AUD	AIRES	s (I11) RY Test CI		en to subje		O be retu	urned			HA CI tu	urned o	HA off

SUBJECT ID:_____ SEEN BY MONITOR: _____

__ DATE: ____/__

ELEPHANT (METO	18-028) Versi	on: 3.2	Name in	vestiga	tor:			Sign	ature:		
Completed?												
		Test		Retest		Test		Retest				
Listening		CIHA		CIHA		CIHA		CIHA				
CI processor		Δ		Δ		O		0				
CI program												
HA program		T		Bimo	dal fit	Ι	Π	1				
Level (dB SPL)	55	65	75	65	55	65	75	65				
Completed?												
Remarks]			
					BRE	AK						
2.11.6. MATRIX IN	QUIET											
	Prac	tice		Test		Retes	t	Test		R	etest	
Listening				CI		CI		CI			CI	
CI processor	Δ,	<u> </u>		Δ		Δ		<u>O</u>			<u>O</u>	
CI program		•••										
HA program					НА	turne	d off			I		
N sentences	10	10		10		10		10			10	
Word list nr.												
Order	1	L										
Completed?												
Remarks												
UBJECT ID:		SEEN	ву мо	NITOR: _				DATE:		/	/	

ELEPHANT (MET	C 18-0	28) Ve	rsion: 3	3.2 Name	investigato	r:		Signa	iture:	
2.11.7. MATRIX IN	I NOISE									
	Prac	ctice	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI/	CIHA	CI	CI	CIHA	CIHA	CI	CI	CIHA	CIHA
CI processor	Δ	,	Δ	Δ	Δ	Δ	0	0	0	0
CI program								••••		
HA program		f/ odal		turned off	Bimodal fit	Bimodal fit		urned off	Bimodal fit	Bimodal fit
N sentences	10	10	10	10	10	10	10	10	10	10
Word list										
Order										
Completed?										
Test result (SRT in dB SNR)										
Mean result (SRT in dB SNR)										
Remarks										
					BREA	<				

SUBJECT ID:	SEEN BY MONITOR:	 DATE:	/	/	

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

2.11.8. MATRIX IN NOISE SPATIAL

	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CI							
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor	Δ	Δ	Δ	Δ	0	0	0	0
CI program								
HA program				HA tu	rned off			
N sentences	10	10	10	10	10	10	10	10
Hammerfall								
Word list		•••••	•••••		•••••		•••••	
Order								
Completed?								
	Test	Retest	Test	Retest	Test	Retest	Test	Retest
Listening	CIHA							
Spatial	SONCI	SONCI	SONHA	SONHA	SONCI	SONCI	SONHA	SONHA
CI processor	Δ	Δ	Δ	Δ	0	0	0	0
CI program								
HA program	Bimodal fit							
N sentences	10	10	10	10	10	10	10	10
Preset								
Word list								
Order								
Completed?								

Completed?						
SUBJECT ID:_	 SEEN BY M	IONITOR: _	 1	DATE:		
					Page	52 of 110

ELEPHANT (METC 18-028) Ve	rsion: 3.2 Name inves	tigator:	Signature:	
Remarks				
2.11.9. PROTOCOL DEVIATIONS				
Were there any protocol devi		Yes	□No	
	ations:	<u></u> 1€5		
Remarks				
2.11.10. DEVICE DEFICIENCIES				
Were there any device deficie	encies?	Yes	☐ No	
Romarks				
2.11.11. ADVERSE EVENTS				
Checked and acted on advers	e events?	Yes	∐ No	
Remarks				
General remarks				
SUBJECT ID:SEE	N BY MONITOR:		_ DATE://_	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator: _	Si _{	gnature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE:	

ELEPHANT (MET	C 18-028	3) Versior	n: 3.2 Nar	ne inve	stigator	:		Signature	2:
2.12. Visit F1	1 (wee	k 12)							
	Date:				./	/			
Bimodal	user:		Yes	☐ No,	becaus	e			
2.12.1. LISTENING	EFFORT								
		Pra	ctice	Te	est	Test		Test	Test
Listening			CIHA			CI		CIHA	CIHA
CI process		Δ,	/ O	L	7	0		Δ	0
CI prograr	n	•••							
HA progra	m	Off / b	imodal		НА	off		Bimodal fit	Bimodal fit
N		,	1	Ę	5	5		5	5
SRT input (in di -> See visit I	-		·····				·····		
Order		•••							
Completed	1?]				
Remarks									
2.12.2. LOUDNESS	SCALING	G							
	Ta	est	Tes	+		est			
Listening		CI	CI			HA			
CI processor		Δ	0						
CI program					С	l off			
HA program		НА	off			odal fit			
N frequencies	4	4	4			4			
Order									
Completed?]	ı				
Remarks									
CUDIFCT ID.			V MONITO					ATF: /	

ELEPHANT (METC 1	.8-028) Version: :	3.2 Name investi	gator:	Signature	e:
2.12.3. SMRT					
	Test	Retest	Test	Retest	
Listening	Cl	Cl	CI	CI	
Cl processor	Δ	Δ	O	O	
CI program					
HA program		HA tur	rned off		
Completed?					
Remarks					l
2.12.4. PREFERENCE	SCALES				
Preference scales (i	03) completed?	Yes	☐ No		
2.12.5. FITTING					
Particularities from	previous fitting	to be taken into	account? 🗌 No	Yes, see fitti	ng form
Fitting form (i02) co	ompleted?	Yes	☐ No		
Particularities relev	ant for next fitti	ng? No	Yes, note on	fitting form	
Compliance forms of	completed?	Yes	☐ No		
Consequences of Cl (Appendix Complian		asurements, bas	ed on calculations	(fitting form) and	cut-off points
Study co	ontinuation	Remove	d from CI per prot	ocol population	
☐ Early te	rminated and tra	ansferred to clini	cal care		
Remarks					
2.12.6. SPEECH THER	APY				
Particularities from		to be taken into	account? No	Yes, note he	ere
Remarks					
l			T A IZ		
		BR	EAK		
SUBJECT ID:	SEEN BY N	MONITOR:		DATE:/	

Listening CI	Listening CI CI CI CI CI CI processor	Test	Test	Test	Test				sion: 3.2 N					Sign	
Listening	Listening	Ci	Ci	Listening	Listening	2.12.7. SPEECH A	UDIOME	TRY							
Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl <td>Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □</td> <td>Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □</td> <td>Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl<td>Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl<td></td><td>Te</td><td>st</td><td>Retest</td><td></td><td>Test</td><td></td><td>Retest</td><td></td><td></td></td></td>	Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl <td>Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl<td></td><td>Te</td><td>st</td><td>Retest</td><td></td><td>Test</td><td></td><td>Retest</td><td></td><td></td></td>	Cl program HA program HA turned off Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl <td></td> <td>Te</td> <td>st</td> <td>Retest</td> <td></td> <td>Test</td> <td></td> <td>Retest</td> <td></td> <td></td>		Te	st	Retest		Test		Retest		
Cl program HA program Level (dB SPL) 75 65 55 65 75 65 55 65 Completed?	Cl program	Cl program HA program Level (dB SPL) 75 65 55 65 75 65 55 65 Completed?	Cl program HA program Level (dB SPL) 75 65 55 65 75 65 55 65 Completed?	Cl program	Cl program	Listening	C	1	CI		CI		CI		
HA program HA turned off	HA program HA turned off	HA program HA turned off	HA program HA turned off	HA program HA turned off	HA program HA turned off	CI processor		7	Δ		0		0		
Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl<!--</td--><td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>CI program</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td></td></td></td></td>	Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl<!--</td--><td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>CI program</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td></td></td></td>	Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks Practice Test Retest Test Retest Listening Cl Cl </td <td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>CI program</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td></td></td>	Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>CI program</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td></td>	Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>CI program</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td>	Level (dB SPL) 75 65 55 65 75 65 55 65 Completed? □ □ □ □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>CI program</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	CI program									
Remarks Practice Test Retest Test Retest Listening Cl Test Retest Netest Cl Test Net <stable by<="" td=""> Listenion<</stable>	Remarks Practice Test Retest Test Retest Listening Cl Test Retest Netest Test Retest Cl <	Completed? □ □ □ □ Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl	Remarks Practice Test Retest Test Retest Listening Cl Test Retest Netest Cl Test Net <stable by<="" td=""> Listenion<</stable>	Remarks Practice Test Retest Test Retest Listening Cl Test Retest Netest Test Retest Cl <	Remarks Practice Test Retest Test Retest Listening Cl Test Retest Netest Test Retest Cl <	HA program			HA tur	ned o	ff				
Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening CI	Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl	Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening CI	Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening CI	Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl	Remarks 2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl	Level (dB SPL)	75 6	5 55	65	75	65	55	65		
2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl All	2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening CI A A O O O O O O O A A A O D D A A A A A A A A A A A A A A A A <</td> <td>2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl All All All All All All All All All All</td> <td>2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Completed?</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td></td>	2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening CI A A O O O O O O O A A A O D D A A A A A A A A A A A A A A A A <	2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl All	2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl<td>Completed?</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td>	2.12.8. MATRIX IN QUIET Practice Test Retest Test Retest Listening Cl Cl <td>Completed?</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	Completed?									
Practice Test Retest Test Retest Listening CI A A A CI CI CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Practice Test Retest Test Retest Listening CI A A A CI CI CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Practice Test Retest Test Retest Listening CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Practice Test Retest Test Retest Listening CI A A A CI CI CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Practice Test Retest Test Retest Listening CI A A A CI CI CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Practice Test Retest Test Retest Listening CI A A A CI CI CI A A A A A A A A A A A A A A A A A A A A A A A A A A A A A A	Remarks		I		<u> </u>					
Listening CI	Listening CI	Listening CI	Listening CI	Listening CI	Listening CI	2.12.8. MATRIX II	N QUIET								
CI processor △ / O △ △ O O CI program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed? □ □ □ □ □	CI processor \$\Delta\$ / \$\O\$ \$\Delta\$ \$\O\$ \$\O\$ CI program HA program HA off N sentences 10 10 10 10 10 Word list nr. Order 1 Completed?	CI processor △ / O △ △ O O CI program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed? □ □ □ □ □	CI processor △ / O △ △ O O CI program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed? □ □ □ □ □	CI processor \$\Delta\$ / \$\O\$ \$\Delta\$ \$\O\$ \$\O\$ CI program HA program HA off N sentences 10 10 10 10 10 Word list nr. Order 1 Completed?	CI processor \$\Delta\$ / \$\O\$ \$\Delta\$ \$\O\$ \$\O\$ CI program HA program HA off N sentences 10 10 10 10 10 Word list nr. Order 1 Completed?		Pra	actice	1	Гest		Re	etest	Test	Retest
Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	Cl program HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?		Λ								
HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?	HA program HA off N sentences 10 10 10 10 Word list nr. Order 1 Completed?		Δ	/ U		Δ			Δ	U	
N sentences 10 10 10 10 10 Word list nr.	N sentences 10 10 10 10 Word list nr. Order 1 Completed?	N sentences 10 10 10 10 Word list nr. Order 1 Completed?	N sentences 10 10 10 10 Word list nr. Order 1 Completed?	N sentences 10 10 10 10 Word list nr. Order 1 Completed?	N sentences 10 10 10 10 Word list nr. Order 1 Completed?								A off		
Order 1 Completed? </td <td>Order 1 Completed? </td> <td>Order 1 Completed? <!--</td--><td>Order 1 Completed? </td><td>Order 1 Completed? </td><td>Order 1 Completed? </td><td></td><td>10</td><td>10</td><td></td><td>10</td><td></td><td></td><td></td><td>10</td><td>10</td></td>	Order 1 Completed?	Order 1 Completed? </td <td>Order 1 Completed? </td> <td>Order 1 Completed? </td> <td>Order 1 Completed? </td> <td></td> <td>10</td> <td>10</td> <td></td> <td>10</td> <td></td> <td></td> <td></td> <td>10</td> <td>10</td>	Order 1 Completed?	Order 1 Completed?	Order 1 Completed?		10	10		10				10	10
Completed?	Completed?	Completed?	Completed?	Completed?	Completed?	Word list nr.							•••••		
						Order		1							
Remarks	Remarks	Remarks	Remarks	Remarks	Remarks	Completed?									
						Remarks			•						

SUBJECT ID:__

____ SEEN BY MONITOR: __

DATE: ____/__

ELEPHANT (MET	C 18-028	3) Versio	Sign	ature:				
2.12.9. MATRIX IN	I NOISE							
	Prac	ctice	Test	Retest	Test	Retest		
Listening	C	Cl	CI	CI	CI	CI		
CI processor	Δ	<u> </u>	Δ	Δ	0	0		
CI program								
HA program			1	HA off		T		
N sentences	10	10	10	10	10	10		
Word list nr.								
Order	2	1						
Completed?								
Test result (SRT in dB SNR)								
Mean result (SRT in dB SNR)								
Remarks					I			
			E	BREAK				
2.12.10. QUESTIO	NNAIRES							
			Returned and c	hecked?				
Da	ite		//.					
Sound quality d	escripto	rs (I11)						
Remarks			1					
2.12.11. PROTOCO	DL DEVIA	TIONS						
Were there any			ons?	Yes	☐ No			
Remarks								
SUBJECT ID:		_ SEEN B	Y MONITOR:		DATE:	<i></i>		

ELEPHANT (METC 18-02	28) Version: 3.2 Name inve	stigator:	Signature:	
2.12.12. DEVICE DEFICIEN	NCIES			
Were there any device Remarks	deficiencies?	Yes	No	
2.12.13. ADVERSE EVENT	'S			······································
Checked and acted on a	adverse events?	Yes	☐ No	
Remarks				
General remarks				
SUBJECT ID:				

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE:/

C 10-020) versi	on: 3.2 N	iame i	nvest	igato	r:	Signature:			
2 (weel	k 16)									
Date:			•••		/	/				
l user:		Yes		No, b	ecaus	se				
ICE SCALE	S			ė		-	-		_	
es (i03) co	mplet	ed?	Ye	es		☐ No				
FITTING										
alogging 8	& impe	dances (i02) c	omple	eted?	Yes] No	
ns compl	eted?		Ye	es		☐ No				
UDIOMET	RY									
		Datast		Ta		Datast				
	[
		_		<u>Ci</u>		0				
		HA tur	ned o	ff						
75 65	55	65	75	65	55	65				
					<u> </u>					
N QUIET										
Prac	tice	1	Гest		R	etest	Te	st	Retest]
			CI			CI			CI	
Δ	0		Δ			Δ)	0	_
								•••		
10	4.5		16		Н			^	10	-
10	10		10			10	1	U	10	1
1	L									-
1		ı					1			
	Date: I user: ICE SCALE es (i03) cc PITTING alogging & ms comple UDIOMET Test CI 75 65 Prace CO A 10 10	2 (week 16) Date: I user: I	2 (week 16) Date:	2 (week 16) Date:	2 (week 16) Date:	2 (week 16) Date:	2 (week 16) Date:			

ELEPHANT (MET	C 18-028	3) Versio	Signature:				
2.13.5. MATRIX IN	NOISE						
	Pra	ctice	Test	Retest	Test	Retest	
Listening	(CI	CI	CI	CI	CI	
CI processor	Δ,	<u>/ O</u>	Δ	Δ	0	0	
CI program							
HA program				HA turned off			
N sentences	10	10	10	10	10	10	
Word list nr.							
Order		1					
Completed?							
Remarks	<u> </u>						
					•••••		
2.13.6. DATA MAI	NAGEME	NT CHECK	(-UP				
Digital data com	plete an	d correct	ly archived on ne	etwork drive?	Yes	☐ No	
→ If no, describe	stens to	n he take	n:				
,, accomb							
							••••
Source documen	its corre	ctly archi	ved in filing cabi	net?	Yes	No	
→ If no, describe	e steps to	o be take	n:				
		cane					
		•••••					••••
							· • • • •
Remarks							
2.13.7. PROTOCO	L DEVIAT	IONS					
Were there any	protocol	deviatio	ns?	Yes	No		
Remarks							
2.13.8. DEVICE DE	FICIENCI	ES					
SUBJECT ID:		SEEN B	Y MONITOR:		DATE:	/ /	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investi	gator:	Signature:	
Were there any device o	deficiencies?	Yes	No	
Remarks				
2.13.9. ADVERSE EVENTS				
Checked and acted on a	dverse events?	Yes	☐ No	
Any signs of tinnitus?		Yes	☐ No	
If yes, on what side(s)		Left	Right	
If yes, to what extent (V	AS 0-10)?	Left:	Right:	
Any signs of vertigo?		Yes	No	
Any signs of oscillopsia?		Yes	No	
Remarks				
General remarks				
SUBJECT ID:	SEEN BY MONITOR:		DATE: / /	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	_ DATE:/

ELEPHANT (MET	C 18-028)	Versio	n: 3.2 N	ame inv	estigato	or:	Sig	nature:
2.14. Visit F1	3 (week	20)						
	Date:	Γ			/	/		
		L			<u> </u>	<u> </u>		
Bimoda	l user:] Yes	☐ No	, becaus	se		
2.14.1. PREFEREN	ICE SCALES							
Preference scale	es (i03) con	npleted	d?	Yes		☐ No		
2.14.2. FITTING								
Particularities fr	om previo	us fittir	ng to be	taken i	nto acco	ount? 🔲 N	No Yes, s	ee fitting form
Fitting form (i02	.) complete	ed?		Yes] No		
Particularities re	elevant for	next fi	tting?	□No		Yes, note	e on fitting form	
Compliance forr			-	Yes	_	No	-	
	complet	.cu:		1.63		1140		
Remarks								
2.14.3. SPEECH A	LIDIOMETR	······································						
2.14.3. SPEECH A	ODIOWETK	<u> </u>						
	Test		Retest		est	Retest		
Listening CI processor	CI		CI			CI		
	Δ		Δ		<u> </u>	U		
CI program								
HA program	75 65			ned off		65		
Level (dB SPL)	75 65	55	65	75 6	55 55	65		
Completed?								
Remarks				<u> </u>				
2.14.4. MATRIX II	N QUIET							
	Practi	ice	Т	Гest	R	etest	Test	Retest
Listening	CI			CI		CI	CI	CI
CI processor	Δ/	<u>O</u>		Δ		Δ	0	
CI program								
HA program	40	10		10	HAt	urned off	40	40
N sentences	10	10		10		10	10	10
								i
Word list nr. Order	1		•					

ELEPHANT (METO	18-028)	Version	: 3.2 Name inves	stigator:	Sign	gnature:		
Completed?								
Remarks								
2.14.5. MATRIX IN	NOISE							
-	Pra	ctice	Test	Retest	Test	Retest		
Listening	(CI	CI	CI	CI	CI		
CI processor	Δ,	<u>/ O</u>	Δ	Δ	0	0		
HA program		T		HA turned off		I		
N sentences	10	10	10	10	10	10		
Word list nr.								
Order		1						
Completed?								
Remarks								
2.14.6. PROTOCOL	DEVIATIO	ONS						
Were there any p			ns?	Yes	☐ No			
Remarks								
2.14.7. DEVICE DE	FICIENCIE	S						
Were there any o	levice de	ficiencie	s?	Yes	☐ No			
Remarks								
2.14.9. ADVEDSE F	VENTS						i	
2.14.8. ADVERSE E								
Checked and acte	ea on adv	verse eve	ents?	Yes	∐ No			
Remarks								
SUBJECT ID:		SEEN BY	MONITOR:		DATE:	//_		

ELEPHANT (METC	18-028) Version: 3.2 Name investigator:	Signature:
General remar	ks	
·····		
SUBJECT ID:	SEEN BY MONITOR:	DATE:/

ELEPHANT (METC 18-028	8) Version: 3.2 Name investigator:	Signature:	_
SUBJECT ID:	SEEN BY MONITOR:	DATE:/	

ELEFTIANT (WET	C 10-U28	y versior	n: 3.2 Name inve	sugator:			Signature:		
2.15. Visit F14	4 (wee	k 26)							
1	Date:			/	/				
Bimodal	user:		Yes No,	because					
2.15.1. TONE AUD	IOMETR'	Υ			-			-	
	(Cl	НА	Una	ided				
Processor/Ear	Δ	0	Bimodal fit	L	R				
CI program			CI off	CI off	CI off				
Completed?									
Remarks									
2.15.2. SPEECH AL	JDIOMET	RY							
		ided							
Ear	L	R							
Completed?									
Remarks			I 						
2.15.3. PREFERENCE	CE SCALE	c							
Preference scales			d? ☐ Yes] No				
SUBJECT ID:		SEEN D	Y MONITOR:			DATE:		/	

ELEPHANT (METC 18	3-028) Version: 3.2 N	or:	S	ignature:	
2.15.4. FITTING					
Program choice after shared decision making:			Standar	d program	Natural program
Fitting form (i02) completed?			Yes	☐ No	
Compliance forms completed?			No		
Consequences of HA		ements, based	on calculation	ons (fitting fo	rm) and cut-off points
Study co	ntinuation	Removed fr	om HA popu	ılation/bimod	dal group?
ECAP completed?			Yes	☐ No	
Spare processor take	en in and stored?		☐ No	Yes	-> S/N:
Remarks					
2.15.5. QUESTIONNAI	RES	1			
	Given to subject	To be return	ned		
Date	/				
SSQ-12 (I07)					
HUI-3 (I08)		Visit F15			
ICECAP-A (09)					
Sound quality descriptors (I11)					
Remarks					
		DDEA			
2.15.6. PROTOCOL DE	VIATIONS	BREA	.r.		-
Were there any prot			Yes	□No	
Remarks			_		
SUBJECT ID: SEEN BY MONITOR:				DATE:	

ELEPHANT (METC 1	8-028) Version: 3.2 Name inv	Signature:		
2.15.7. DEVICE DEFIC	IENCIES			
Were there any dev	ice deficiencies?	Yes	No	
Remarks				
2.15.8. ADVERSE EVE				
Checked and acted	on adverse events?	Yes	☐ No	
Remarks				
General remark	e			
,				
······				
SUBJECT ID:	SEEN BY MONITOR:		DATE: / /	

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	_ DATE:/

	Date:	:			•		./	/.					
Bimoda	l user:	:] Yes] No							
16.1. SPEECH A	UDION	METRY											
		Test		Rete	est		Tes	t	Retest		Test		Retest
Listening		CI		CI			НА		НА		CIHA		CIHA
CI processor	Pr	eferre	ed	Prefer		CI t	urned	off	Pr	eferre	ed	Preferred	
CI program							CI t	CI turned off					
HA program		HA 1	turne	d off		Bimodal fit			Bir	nodal	Bimodal fit		
evel (dB SPL)	75	65	55	65		75	65	55	65	75	65	55	65
Completed?]								
emarks				<u> </u>									
16.2. MATRIX I	N QUIE	ET											
	Prac	ctice	Т	est	Re	etest							
Listening	(CI		CI		CI							
CI processor	Prefe	erred	Pre	ferred	Pre	ferred	i						
CI program													
HA program		HA turned off											
N sentences	10	10		10		10							
Word list nr													
Order	:	1		2		3							
Completed?					[
·													
Remarks													

Practice Test Retest Test Retest		 						
Listening CI / CIHA CI Preferred CI Preferred Preferred Preferred Preferred CI program processor CI program processor HA program program program processor Off / bimodal processor HA turned off processor Bimodal fit processor Bimodal fit processor Word list nr processor Order processor Completed? processor Test result processor Mean presult processor	Listening	Pra	actice		ı			
CI	Listening	l	JULIUE	Test	Retest	Test	Retest	
processor Preferred Preferred Preferred Preferred Preferred CI program HA program Off / bimodal HA turved off Bimodal fit Bimodal fit N sentences 10 10 10 10 10 Word list nr Order Completed? Mean result (SRT in dB SNR)	8	CI /	/ CIHA	CI	CI	CIHA	CIHA	
HA program Off / bimodal HA turned off Bimodal fit Bimodal fit N sentences 10 10 10 10 10 Word list nr Order Completed? Mean result (SRT in dB SNR)		Pre	ferred	Preferred	Preferred	Preferred	Preferred	
N sentences 10 10 10 10 10 10 Word list nr Order Completed? Test result (SRT in dB SNR) Mean result (SRT in dB SNR)	CI program							
sentences 10 10 10 10 Word list nr Order Completed? Test result (SRT in dB SNR) Mean result (SRT in dB SNR)	HA program	Off /	bimodal	HA tur	ned off	Bimodal fit	Bimodal fit	
Order		10	10	10	10	10	10	
Completed?	Word list nr							
Test result (SRT in dB SNR)	Order							
(SRT in dB SNR)	Completed?							
result								
emarks	result							
	emarks							

SUBJECT ID:	SEEN BY MONITOR:	DATE:	,	/	

ELEPHANT (METC 18	-028) Version: 3.2 N	ame investigator:	Signature:	
2.16.4. QUESTIONNAI	RES			
	Returned and checked			
Date	/			
SSQ-12 (I07)				
HUI-3 (108)				
ICECAP-A (09)				
Sound quality descriptors (I11)				
Remarks		<u></u>		
SUBJECT ID:	SEEN BY MONI	TOR	DATE:/	

ELEPHANT (ME	TC 18-028)	Version: 3.2	Name inves	tigator:		Signatu	ıre:	
2.16.5. MATRIX	IN NOISE SPA	ATIAL						
	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 tur	ned 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?								
Remarks								
			В	REAK				

SUBJECT ID:	SEEN BY MONITOR:	DATE:	,	/	

ELEPHANT (MET	C 18-028) Versior	n: 3.2 Name inve	stigator: _	Signa	ture:
2.16.6. LISTENING	i EFFORT	1			
		Practi	ce	Test	Test
Lis	Listening		НА	CI	CIHA
CI pr	CI processor		ed	Preferred	Preferred
CI p	CI program				
НА р	HA program		odal	HA turned off	Bimodal fit
SRT input	t (in dB SNR)				
C)rder				
Com	pleted?				
Remarks					
2.16.7. LOUDNESS	S SCALING				
	Test	Test			
Listening	CI	НА			
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?					
Remarks					
SUBJECT ID:	CEENI DI	/ MONITOR:			/

ELEPHANT (ME	TC 18-028) Ver	sion: 3.2 Name	investigator: _		Signature:
2.16.8. SMRT					
]
	Test	Retest	Test	Retest	
Listening	CI	CI	HA	HA	
CI processor	Preferred	Preferred	CI turr		
CI program			CI turr		
HA program	HA tur	ned off	Bimo	dal fit	
Completed?					
Remarks					
2.16.9. PROTOC	OL DEVIATIONS				
Were there any	y protocol devi	ations?		Yes] No
Remarks					
2.16.10. DEVICE	DEFICIENCIES				
Were there any		ncios		Yes] No
Remarks	y device deficie	iicies:	Ш	Te5] 110
2.16.11. ADVERS	SE EVENTS				
Checked and a	cted on adverse	e events?		Yes] No
Remarks					
General rem					
General ren					
l					
SUBJECT ID:	SEE	N BY MONITOR	·	DAT	E:/

3. Second p	hase		
3.1. Visit S1 (we	ek 30)		
Date	e:	/	
Bimodal use	r: Yes	No, because	
.1.1. PREFERENCE SC	_		
reference scales (i0		Yes N	lo
.1.2. FITTING			
Particularities from p	previous fitting to be	taken into account?	No Yes, see fitting form
itting form (i02) cor	npleted?	Y	es No
Compliance forms co	ompleted?	Yes No	
articularities releva	nt for next fitting?	☐ No ☐ Yes	, note on fitting form
Remarks			
.1.3. QUESTIONNAIR	ES	T	1
	Given to subject	To be returned	
Date	/	Visit T1	
SSQ-12 (I07)			
HUI-3 (I08)			
ICECAP-A (09)			
Sound quality descriptors (I11)			
-			

Ci	Ci	.4. SPEECH AUI											
Cl processor Preferred Preferred Cl turned off Preferred Preferred Cl turned off Preferred Prefe	Cl processor Preferred Preferred Cl turned off Preferred Preferred Cl turned off Cl turned off	Listoning		Test		Retest		Test		Retest		Test	Retest
Cl program	Cl program		Pre		-d				rned (Pr		
HA program	HA program										<u> </u>		
Practice Test Retest	Practice Test Retest				_								
Completed?	Completed?		75				75						
Practice Test Retest	Practice Test Retest		73		3						73		
Practice Test Retest	Practice Test Retest	marks											
Listening CI CI CI CI processor Preferred Preferred CI program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	Listening CI CI CI CI processor Preferred Preferred Preferred CI program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?												
Listening CI CI CI CI processor Preferred Preferred Program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	Listening CI CI CI CI processor Preferred Preferred Preferred CI program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	L.5. MATRIX IN (QUIET										
Listening CI CI CI CI processor Preferred Preferred Program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	Listening CI CI CI CI processor Preferred Preferred CI program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?			Drast	ico	Tost			Doto]			
Cl processor Preferred Preferred Cl program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	Cl processor Preferred Preferred Cl program HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?			Pract	ice	rest	•		Ketes	st			
CI program HA turned off N sentences 10 10 10 10 Word list nr Order 1 2 3 Completed?	CI program	Listening		CI		CI			CI				
HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	HA program HA turned off N sentences 10 10 10 Word list nr Order 1 2 3	CI processor	P	refer	red	Prefer	red	F	referi	ed			
N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	N sentences 10 10 10 Word list nr Order 1 2 3 Completed?	CI program			•		•••						
Word list nr Order 1 2 3 Completed?	Word list nr Order 1 2 3 Completed?	HA program				HA turne	ed off						
Order 1 2 3 Completed?	Order 1 2 3 Completed?	N sentences	10	0	10	10			10				
Completed?	Completed?	Word list nr											
		Order		1		2			3				
emarks	Remarks	Completed?											
		emarks	•			•		•		-			

.1.6. MATRIX I	N NOIS	E		_				
		actice	Test	Retest	Test	Retest		
Listening	CI	/ CIHA	CI	CI	CIHA CIHA			
CI processor	Preferred		Preferred		Preferred	Preferred	Preferred	Preferred
CI program								
HA program	Off /	loudness	HA tur	ned off	Loudness fit	Loudness fit		
N sentences	10	10	10	10	10	10		
Word list nr								
Order								
Completed?								
Test result (SRT in dB SNR)								
Mean result (SRT in dB SNR)								

ELEPHANT (ME	TC 18-028)	Version: 3.2	Name inves	tigator:		Signatu	ıre:	
3.1.7. MATRIX I	N NOISE SPA	TIAL						
	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 tur	ned 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?								

	Remarks				
Ι		 	 		
1					
1					

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

Practice Test Test Listening CI / CIHA CI CIHA CI processor Preferred Preferred CI program HA program Off / Loudness fit HA turned off Loudness fit SRT input (in dB SNR)	ELEPHANT (MET	C 18-028) Version	n: 3.2 Name inves	tigator:	_Signature:
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)						
Listening CI / CIHA CI CIHA CI processor Preferred Preferred Preferred CI program	3.1.8. LISTENING I	EFFORT				
Cl processor				Practice	Test	Test
Cl program	Listening	S		CI / CIHA	CI	CIHA
HA program Off / Loudness fit HA turned off Loudness fit SRT input (in dB SNR)	CI program HA program Off SRT input (in dB SNR) Order			Preferred	Preferred	Preferred
SRT input (in dB SNR) Order						
Order			Off	/ Loudness fit	HA turned off	Loudness fit
Order						
Remarks 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?			••••			
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?						
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?	Remarks					
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?						
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?	.1.9. LOUDNESS	SCALING				
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?		Te	est	Test		
CI program CI turned off HA program HA turned off Loudness fit N questions 4 4 Word list nr Order Completed?	Listening	C	Cl	НА		
HA program HA turned off Loudness fit N questions 4 4 Word list nr Order Completed?	CI processor	Prefe	erred	CI turned off		
N questions 4 4 Word list nr Order Completed?	CI program			CI turned off		
Word list nr Order Completed?	HA program	HA tur	ned off	Loudness fit		
Order Completed?	N questions	2	1	4		
Completed?	Word list nr					
	Order					
Remarks	Completed?					
	Remarks			<u>. </u>		
	SUBJECT ID:		SEEN R	Y MONITOR:	DATE:	1 1

3.1.10. DATA MANAGEMENT CHECK-UP				
Digital data complete and correctly archived on netwo	rk drive?		Yes	☐ No
\rightarrow 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? Remarks	Yes		No	
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)?	I	Left:	1	Right:
Any signs of vertigo	[Yes	[No
Any signs of oscillopsia?	[Yes	[No
SUBJECT ID: SEEN BY MONITOR:		DA1	<u></u> ΓΕ:	

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

ELEPHANT (METC 1	.8-028) Version: 3.2 Name investigator:	Signature:
Remarks		
0		
General remark	(S	
SUBJECT ID:	SEEN BY MONITOR:	DATE: / /

ELEPHANT (METC 18-02	8) Version: 3.2 Name investigator:	Signature:
SUBJECT ID:	_ SEEN BY MONITOR:	DATE:/

4. Third phase 4.1. Visit T1 (week Date: Bimodal user: 4.1.1. TONE AUDIOMETR HA Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME	34) [Yes	<u> </u>							
Bimodal user: 4.1.1. TONE AUDIOMETR HA Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME	Y		<u> </u>							
Bimodal user: 4.1.1. TONE AUDIOMETR HA Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME			<u> </u>							
4.1.1. TONE AUDIOMETR HA Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME		Yes] No, b	ecau	se					
4.1.1. TONE AUDIOMETR HA Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME		Yes	No, b	ecau	se					
Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME										
Program Loudne Completed? Remarks 4.1.2. SPEECH AUDIOME										
Completed? Remarks 4.1.2. SPEECH AUDIOME	ss fit									
Remarks 4.1.2. SPEECH AUDIOME										
4.1.2. SPEECH AUDIOME										
	EDV									
-	IRY	Г								
	est	Retest		Test		Retest		Test		Retest
Listening CI processor Pre	CI ferred	CI Preferred		HA Cl tui	ned o	HA off		CIHA eferre	ed	CIHA Preferred
CI program					ned o					
HA program	HA turne	d off			ness		Lou	dnes		Loudness fit
	65 55	65	75	65	55	65	75	65	55	65
Completed?										
Remarks										

SUBJECT ID:_____ SEEN BY MONITOR: ____

_ DATE: ___

ELEPHANT (METO	ELEPHANT (METC 18-028) Version: 3.2 Name investigator:Signature:												
4.1.3. MATRIX IN (QUIET												
	Prac	tice	Test	R	etest								
Listening	C	:I	CI		CI								
CI processor	Prefe	erred	Preferre	d Pre	ferred								
CI program													
HA program			HA turned	off									
N sentences	10	10	10		10								
Word list nr													
Order	1	<u> </u>	2		3								
Completed?													
Remarks	Remarks												
	A A MATRIX III MOISE												
4.1.4. MATRIX IN NOISE													
	Practice		Test	Retest	Test	Retest							
Listening	CI /	CIHA	CI	CI	CIHA	CIHA							
CI processor	Pref	ferred	Preferred	Preferred Preferred		Preferred							
CI program													
HA program		off / dness	HA tur	ned off	Loudness fit	Loudness fit							
N sentences	10	10	10	10	10	10							
Word list nr.													
Order													
Completed?													
Test result (SRT in		·····											
Mean result (SRT in dB SNR)													
SUBJECT ID:		SEEN B	Y MONITOR	·		DATE:	<i></i>						

ELEPHANT (METC 1	8-028) Version: 3.2 Na	me investigator:	Signa	ture:
emarks				
1.5. QUESTIONNAIF	RES			
	Returned and checked			
Date	/			
SSQ-12 (I07)				
HUI-3 (I08)				
ICECAP-A (09)				
Sound quality descriptors (I11)				
emarks				
		BREAK		
		DREAR		
UBJECT ID:	SEEN BY MONIT	OR:	DATE: /	/

ELEPHANT (METC 18-028) Version: 3.2 Name investigator:Signature:												
4.1.6. MATRIX I	N NOISE SPA	TIAL										
	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 tur	ned 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?												
Remarks	<u> </u>											
4.1.7. LISTENING	G EFFORT							7				
		Practic	е	Tes	t	T	est					
Listening	3	CI / CIH	A	CI		CI	IHA					
CI process	or	Preferre	ed	Prefer	red	Pref	erred					
CI progra	m											
HA progra	ım	Off / loud	ness	HA turn	ed off	Loudi	ness fit					
SRT input (in d	B SNR)											
Order												
			l					_				
SUBJECT ID:		SEEN BY MO	NITOR:		DAT	F· /						

ELEPHANT (MET	C 18-028	3) Versior	n: 3.2 Name	inve	stigator:		Signature:	
Completed?	•]		
Remarks								
4.1.8. LOUDNESS	SCALING							
	Te	est	Test					
Listening	(CI	НА					
CI processor	Pref	erred	CI turned of					
CI program		CI turned of		off				
HA program	HA tur	turned off Loudness f		fit				
N questions	,	4						
Word list nr								
Order								
Completed?								
Remarks								
4.1.9. SMRT								
	Test		Retest					
Listening	НА		НА					
CI processor	C	CI turned	off					
CI program	C	CI turned	off					
HA program	l	Loudness	fit					
Completed?								
Remarks								
				P	BREAK			
4.1.10. PREFEREN	CE SCALE	S						
Preference scale			oleted?	Γ	Yes	No		
		-,		_				
SUBJECT ID:		_ SEEN B	Y MONITOR:			DAT	E:/	

4.1.11. FITTING Particularities from pr	evious fittin	g to be ta				
	evious fittin	g to be ta	_			
Turticularities from pr		g to be to	ken into account?		□ Ves	
Fitting form (i02) com	pleted?		Yes	s [No	
Particularities relevan	t for next fit	ting?	No Yes, o	describe he	ere and note on	CRF's next visit
Remarks						
4.1.12. QUESTIONNAIRI	ES					
	Given to s	ubject	To be returned			
Date	/	./			Signature:	
SSQ-12 (I07)						
HUI-3 (I08)			Visit T2			
ICECAP-A (09)						
Sound quality descriptors (I11)						
Remarks						
4.1.13. SPEECH AUDION	METRY					
	Test	Retest				
Listening	CI	CI				
CI processor C	Clinical	Clinical				
CI program						
HA program	HA turned					
Level (dB SPL) 75	65 55	65				
Completed?						
Remarks						
SUBJECT ID:	SEEN BY	/ MONITO	DR:	DA	TE: /	/

ELEPHANT (M	ETC 18-0	28) Version:	3.2 Name inv	
4.1.14. MATRIX	(IN QUI <u>E</u>	Г <u></u>		
	Practic	e Test	Retest	
Listening	CI	CI	CI	
CI processor	Clinica		Clinical program	
CI program				
IA program		HA turned	off	
N sentences	10 1	0 10	10	
Vord list nr.				
Order	1	2	3	
Completed?				
Remarks				
I.1.15. MATRI)	(IN NOIS			
	Prac	tice Tes	t Retest	
Listening	C	I CI	CI	
Cl processor		l		
'	· Clin			
CI program		ram progr		
	prog	ram progr	am prograr	
CI program	prog	ram progr	am program	
CI program	prog	ram progr HA turne	am program	
CI program HA program N sentences	prog	HA turne	am program	
CI program HA program N sentences Word list nr	10	HA turne	am program	
CI program HA program N sentences Word list nr	10	HA turne	am program	
CI program HA program N sentences Word list nr Order Completed?	10	HA turne	am program	
CI program HA program N sentences Word list nr Order Completed?	10	ram progr HA turne 10 10 2	am program	

A.1.16. DATA MANAGEMENT CHECK-UP Digital data complete and correctly archived on network drive?
Digital data complete and correctly archived on network drive?
Source documents correctly archived in filing cabinet?
→ If no, describe steps to be taken:
→ If no, describe steps to be taken: Remarks 4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
→ If no, describe steps to be taken: Remarks 4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
Remarks 4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
4.1.17. PROTOCOL DEVIATIONS Were there any protocol deviations?
Were there any protocol deviations?
Remarks
4.1.18. DEVICE DEFICIENCIES
Were there any device deficiencies?
Nethans
4.1.19. ADVERSE EVENTS Checked and acted on adverse events? Yes No
Any signs of tinnitus?
If yes, on what side(s) Left Right
If yes, to what extent (VAS 0-10)? Left:
Any signs of vertigo?
Any signs of oscillopsia?
Remarks
SUBJECT ID: SEEN BY MONITOR: DATE: / /

ELEPHANT (METC 1	8-028) Version: 3.2 Name investigator:	Signature:
General remark	as s	
SUBJECT ID:	SEEN BY MONITOR:	DATE:/

ELEPHANT (METC 18-028) Version: 3.2 Na				me inv	estig/	gator:				_Signa	ature:		
4.2. Visit T2 (wee	k 52))										
	Date:					/		/					
Pimadal	Bimodal user:												
				Yes		o, bec	Lause.						••••
4.2.1. TONE AUDI	OMET	rry		<u> </u>									
		CI		Н	Α		Unai	ided					
Processor/Ear		Clinica	al	Clin	ical		L	R					
Program				CI	off	С	l off	CI off					
Completed?													
Remarks													
4.2.2. SPEECH AU	DIOM	ETRY											
		Test		Retest		Test		Retest		Test		Retest	
Listening		CI		CI	НА			НА	CIHA		CIHA		
CI processor	(Clinica	al	Clinical	CI turned off			Clinical			Clinical		
CI program													
HA program		HA t	urned	off	Clinical fit			it	Clinical fit		Clinical fit		
Level (dB SPL)	75	65	55	65	75	65	55	65	75	65	55	65	
Completed?													
Remarks													
						BRI	EAK						
4.2.3. QUESTIONN	NAIRE	S											
	Returned		d and										
	checked		ed										
Date			/	./									
SSQ-12 (I07)													
SUBJECT ID: SEEN BY MONITOR:					OR: _				DA	TE: _	/		

LEPHANT (MET	C 18-028	3) Versio	n: 3.2 Name in	vestigator:	Signature:
HUI-3 (I08)					
ICECAP-A (09))				
Sound quality	,				
descriptors (I1	1)				
Remarks					
.2.4. MATRIX IN	QUIET				
	Prac	ctice	Test	Retest	
Listening	(Cl	Cl	CI	
CI processor		nical gram	Clinical program	Clinical program	
CI program					
HA program			HA turned of	f	
N sentences	10	10	10	10	
Word list nr					
Order	-	1	2	3	
Completed?					
	<u>l</u>				I

SUBJECT ID:	_ SEEN BY MONITOR:	DATE:	/	/	

LEEPHANT (METC 18-028) Version: 3.2 Name investigator: Signature: 4.2.5. MATRIX IN NOISE Listening CI / CIHA CI CI CIHA CIHA CIHA CIHA CIHA CI CI CIII CI								
Listening CI / CIHA CI CI CI CINICAL CI C	28) Versi	on: 3.2	Name inv	estigator:			Signature:	
Practice Test Retest Test Retest								
Listening CI / CIHA CI CI CIHA CIHA CI processor Clinical Clinical								
Cl processor Clinical Clinical Clinical Clinical Clinical Clinical Cl program HA program Off / clinical HA turned off Clinical Clinical N sentences 10 10 10 10 10 Word list nr Order Completed? Mean result (SRT in dB SNR)	Prac	ctice	Test	Retest	Test	Retest		
CI program	CI / (CIHA	CI	CI	CIHA	CIHA		
HA program Off / clinical HA turned off Clinical Clinical N sentences 10 10 10 10 Word list nr Order Completed? Mean result (SRT in dB SNR)	Clin	ical	Clinical	Clinical	Clinical	Clinical		
N sentences 10 10 10 10 10 Word list nr Order Completed? Test result (SRT in dB SNR) Mean result (SRT in dB SNR)								
Word list nr	Off / d	clinical	HA tur	ned off	Clinical	Clinical		
Order Completed? Gest result (SRT in dB SNR) Mean result (SRT in dB SNR)	10	10	10	10	10	10		
Completed?								
Test result (SRT in dB SNR) Mean result (SRT in dB SNR)								
Mean result (SRT in dB SNR)								
(SRT in dB SNR)								
Remarks								
							·····	
		Prac CI / C Clin	Practice CI / CIHA Clinical Off / clinical 10 10	Practice Test CI / CIHA CI Clinical Clinical Off / clinical HA tur 10 10	Practice Test Retest CI / CIHA CI inical Clinical Clinical Clinical HA turned off 10 10 10 10 <	Practice Test Retest Test CI / CIHA CI CI CIHA Clinical Clinical Clinical Clinical Off / clinical HA turned off Clinical 10 10 10 10	Practice Test Retest Test Retest CI / CIHA CI CI CIHA CIHA Clinical Clinical Clinical Clinical Clinical Off / clinical HA turned off Clinical Clinical 10 10 10 10 10	Practice Test Retest Test Retest CI / CIHA CI CI CIHA CIHA Clinical Clinical Clinical Clinical Off / clinical HA turned off Clinical Clinical 10 10 10 10 10

SUBJECT ID:	SEEN BY MONITOR:	DATE:/	'	′	

ELEPHANT (METC 18-028)	Version: 3.2 Name investig	gator:	Signature:			
4.2.6. LISTENING EFFORT						
	Practice	Test	Test			
Listening	CI / CIHA	Cl	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?						
Remarks		<u> </u>				
Preference scales (i04 + i004.2.8. FITTING Particularities from previo	o) completed? \(\begin{array}{c} \text{V} \\ \text{U} \\\	res No	5,			
Fitting form (i02) completed?						

ELEPHANT (METC 18-028) Version: 3.2 Name investi	Signature:			
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	work drive?	Yes	☐ No	
\rightarrow If no, describe steps to be taken:				
Source documents correctly archived in filing cabine	t?	Yes	No	
→ If no, describe steps to be taken:				
Remarks				
itemarks				
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				,
CLIDIECT ID: CEEN DV MACNUTOD.		DATE: /		
SUBJECT ID: SEEN BY MONITOR:		DATE:/_	/	

ELEPHANT (METC 1	8-028) Version: 3.2 Name investigator:	Signature:
General remark	(S	
<u> </u>		
CLIBIECT ID.	CEEN DY MONITOD.	DATE: / /

ELEPHANT (METC 18-028) Version	on: 3.2 Name investigator:	Signature:
End of study		
Date of termination of participat	tion in the study:	
Date:	//	
Did there occur early terminatio	n? Yes	□No
If yes, specify the reason of early	y termination.	
(Serious) adverse event	Retraction of infor	med consent
Protocol deviation	Did not conform to	inclusion criteria
☐ No effect of CI	☐ Discompliance to C	CI randomization scheme
Discompliance to other study	y procedures	
SUBJECT ID: SEEN I	BY MONITOR:	DATE:/

ELEPHANT (METC 18-028) Version: 3.2 Na	me investigator:	Signature:
INIVERTION TOD STATE	MENT.	
INVESTIGATOR STATEM	IEN I	
I am confident that the information suppl	ied in this case record f	form is complete and accurate data. I
confirm that the study was conducted in a	accordance with the pro	
that written informed consent was obtain	ed prior to the study.	
Principal investigator:		
rincipal investigator.		
Principal investigator's Signature:		
Date of signature (DD-MM-YYYY):		
SUBJECT ID: SEEN BY MONIT	OR:	DATE:

ELEPHANT (METC 18-028) Version: 3.2 Name investigator:	_Signature:
(SERIOUS) ADVERSE EVENTS (SA/SAE)	

Serious (see *)	Severity	Relationship to study treatment	Action taken regarding study intervention	Outcome of AE
1 = YES	1 = MILD	1 = DEFINITELY related	1 = NONE	1 = RESOLVED, no sequel
2 = NO	2 = MODERATE	2 = POSSIBLY related	2 = DISCONTINUED Permanently	2 = AE still PRESENT – NOT treated
	3 = SEVERE	3 = NOT related	3 = DISCONTINUED Temporarily	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.										
SUB	JECT ID:	SEEN BY MONITOR:		DATE:						

ELEF	PHANT (ME	TC 18-028) Version: 3.2 Name investigator	:	Sign	nature:			
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								

SLIBIECT ID:	SEEN BY MONITOR:	DATE:	 /	/
	-		 	

ELEP	PHANT (METO	C 18-028) Version: 3.2 Name investigator:	S	ignature:		
PRO	TOCOL DEVI	ATIONS				
Nr.	Date	Deviation				
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
SUBJ	JECT ID:	SEEN BY MONITOR:	DATE:			

ELEP	HANT (METC	C 18-028) Version: 3.2 Name investigator:S	ignature:
PRO	TOCOL DEVI	ATIONS	
Nr.	Date	Deviation	
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
SUB.	IECT ID:	SEEN BY MONITOR: DATE:	

ELEPHANT (METC 18-028)	Version: 3.2 Name investigator:	Signature:		
CHANGES IN MEDICATION	USE			
Medication	Start date of use	End date of use	Indication	Subscribed due to (S)AE?
SUBJECT ID:S	SEEN BY MONITOR:	DATE:		

ELEPHANT (METC 18-028) Versi	on: 3.2 Name in	vestigator:	Signature:	
COMPLIANCE				
See SOP Compliance for method	ds and fitting fo	rms for calcula	tions.	
<u>CI</u>				
In the table below it is shown to	what extent su	hiects can sho	ow non-compliance to the CI randomization	schedule before consequences take effect.
THE COURT DETON TE IS SHOWN TO	F4	F7		F11
Study continuation				
Removed from per protocol population		When 2	x >15%	When 2x >15%
Transferred to clinical care	When >40 1	% x When 2 <360 mi	x >25% or >40% x 1 or 1x total usage time n/d	When 2x >25% or >40% x 1 or 1x total usage time <360 min/d
The compliance result that is ca long as compared to the results				counts double since its time window is also double a
<u>HA</u>				
In the table below it is shown to	what extent su	bjects can sho	w non-compliance before they will be remo	oved from the HA population.
	F7	F14		
Study continuation				
No bimodal testing at visit F10	When < 25%			

When < 50%

Removed from HA population

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

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