Clinical Investigation Plan

Investigation Title: A Pre-Marketing, Prospective, Multi-Site, Open-Label, Within-Subject, Feasibility, Interventional Study of Speech Perception with experienced adult cochlear implant recipients using the CP1110 Sound Processor and compared with the CP1000 Sound Processor

Short Title:	**N8 Feasibility**
CIP Number:	**CLTD5804**
Sponsor	**Cochlear Limited** **1 University Ave** **Macquarie University, NSW, 2109** [redacted]

This clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, International Standard ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice, and any regional or national regulations, as applicable.

ClinicalTrials.gov ID: NCT04898673

Manufacturer	Cochlear Limited 1 University Ave Macquarie University, NSW, 2109
Sponsor Organisations	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia Phone: [redacted]
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Safety Contact	[redacted]

A complete list of participating Principal Investigators' names, titles and addresses, and the names and addresses of participating institutions (sites) will be maintained by the Sponsor and will be provided as a separate Principal Investigator List. The definitive Principal Investigator list will be provided in the Clinical Investigation Report.

INVESTIGATOR AGREEMENT

Coordinating Investigator Approval and Declaration

By my signature below, I confirm my review and approval of this Clinical Investigational Plan (CIP).

I also confirm that I will strictly adhere to the requirements therein and undertake to ensure that all staff with delegated responsibilities in the conduct of this CIP have read, understood and will strictly adhere to the requirements therein. This CIP will not be implemented without prior written approval from the Ethics Committee, any applicable National Competent Authorities, and the Sponsor. If amendments to this plan become necessary, written approval by the Ethics Committee and any applicable National Competent Authorities will be obtained before the changes are clinically implemented per the amendment, except under emergency circumstances to protect the rights, safety, and well-being of subjects.

Name	**Title**
[redacted]	Coordinating Investigator
Signature	**Date**

Principal Investigator Declaration

By my signature below, I confirm that I have read, understood and will strictly adhere to the requirements therein. I undertake to ensure that all staff with delegated responsibilities in the conduct of this CIP have also read, understood and will strictly adhere to the requirements therein. This CIP will not be implemented without prior written approval from the Ethics Committee, any applicable National Competent Authorities, and the Sponsor. If amendments to this plan become necessary, written approval by the Ethics Committee and any applicable National Competent Authorities will be obtained before the changes are clinically implemented per the amendment, except under emergency circumstances to protect the rights, safety, and well-being of subjects.

Name	**Title**
	Principal Investigator
Site Name	**Site Address**
Signature	**Date**

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1 DEFINITIONS AND ABBREVIATIONS

Term	Description
ADE	Adverse Device Effect
AE	Adverse Event
AMDT	Approved Medical Device on Test
AuSTIN	Australian Sentence Test in Noise
BEAM	Adaptive beamformer – Microphone directionality
BTE	Behind the ear
CDI	Cochlear Device Interface
CER	Clinical Evaluation Report
CI	Cochlear Implant
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
CNC	Consonant nucleus consonant
COSI	Client Orientated Scale of Improvement
CRF	Case Report Form
CRO	Contract Research Organisation
CTC	Cochlear Technology Centre Belgium
DCF	Data Clarification Form
DD	Device Deficiency
EC	Ethics Committee Synonymous abbreviations/terms include: IRB (Institutional Review Board) IEC (Institutional Ethics Committee or Independent Ethics Committee) HREC (Human Research Ethics Committee)
eCRF	Electronic Case Report Form
FF	ForwardFocus
EDC	Electronic Data Capture
GCP	Good Clinical Practices
GT	Gain threshold. For Noise reduction algorithms. The gain threshold parameter varies the aggressiveness of noise reduction by changing the SNR-dependant attenuation of noisy channels.
IB	Investigator's Brochure
ICF	Informed Consent Form
IDMC	Independent Data Monitoring Committee
IMD	Investigational Medical Device
LIST	Leuven Intelligibility Sentences Test

Term	Description
N7	Nucleus 7 System
N8	Nucleus 8 System
NCA	National Competent Authority
NVA	Nederlandse Vereniging Audiologie
OTE	Off the ear
PI	Principal Investigator
PIL	Principal Investigator List
PMS	Post-Market Surveillance
QoL	Quality of Life
S0N0	Signal and noise from 0 degrees azimuth
S0N90	Signal from 0 degrees and noise from either 90 or 270 degrees azimuth
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SCAN	Automatic Scene Classifier
SNR-NR	Signal to noise ration noise reduction
SOP	Standard Operating Procedure
SP	Sound Processor
SSQ	Speech Spatial and Qualities of Hearing Scale
SRT	Speech Recognition Threshold
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
Zoom	Fixed directional beamformer
4TB	4 talker babble (type of noise)

2 CLINICAL INVESTIGATION SYNOPSIS

Investigation title	A Pre-Marketing, Prospective, Multi-Site, Open-Label, Within-Subject, Feasibility, Interventional Study of Speech Perception with experienced adult cochlear implant recipients using the CP1110 Sound Processor and compared with the CP1000 Sound Processor
Short title	N8 Feasibility
Investigation number	CLTD5804
Name of investigational medical device(s)	Nucleus 8 Sound Processor including: CP1110 Processing Unit CP1110 Rechargeable Battery Modules CP1110 Slimline Coil with CP1000 retention magnets Custom Sound (Version 7.0) CDI Tool (Version 4.20.10.1)
Intended use of investigational medical device(s)	The Nucleus 8 Sound Processor (Model: CP1110) is an unapproved investigational medical device. The intended use for the Nucleus 8 Sound Processor will be the same as for the approved Nucleus 7 Sound Processor: The Nucleus 7 Series Processing Units are intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The processing unit converts sounds into electrical signals, which it sends, via a coil, to an implant. The processing unit also provides power to the implant. When used in combination with an acoustic receiver, the sound processor also delivers sound to the ear canal in recipients with residual hearing
Name and description of comparator device/product(s)	The Nucleus 7 Processing Unit (Model CP1000) is approved for use in Australia and Belgium/Europe.
Estimated recruitment period	2 Months Starting from first enrolment in each country.
Expected duration per subject	Up to 2 Months
Number of subjects planned	20
Number of investigational sites planned	4
Inclusion criteria	1) Aged 18 years or older 2) Post lingually deafened 3) Implanted with the CI600 Series (CI612, CI632, CI622, CI624), CI500 Series (CI512, CI532, CI522) or Freedom Series (CI24RE(CA), CI24RE(ST), CI422) 4) At least 6 months experience with a cochlear implant.

	5) At least 3 months experience with a Nucleus 6 (CP910/920), Kanso (CP950), Kanso 2 (CP1150) or Nucleus 7 (CP1000) Sound Processor 6) Able to score 30% or more at +15 SNR with CI alone on a sentence in babble test 7) Willingness to participate in and to comply with all requirements of the protocol. 8) Fluent speaker in language used to measure speech perception 9) Willing and able to provide written informed consent
Exclusion criteria	1) Additional disabilities that would prevent participation in evaluations. 2) Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedures. 3) Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator. 4) Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling. 5) Cochlear employees or employees of Contract Research Organisations or contractors engaged by Cochlear for the purposes of this investigation. 6) Currently participating,or participated in another interventional clinical study/trial in the past 30 days, or (if less than 30 days) the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation.

Objectives and Endpoints	
Primary Objective	**Primary Endpoint**
To characterise adult cochlear implant speech perception in spatially separated speech and noise (S0N90) with the Nucleus 8 Sound Processor with ForwardFocus ON (BEAM) compared with the Nucleus 7 Sound Processor with ForwardFocus ON (commercial version)	Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (65 dB SPL S0N90 4TB).
Secondary Objective	**Secondary Endpoint**
To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor (SNR-NR on) compared with the Nucleus 7 Sound Processor (SNR-NR on)	Paired difference in percentage CNC/NVA Words correct in quiet (50 dB SPL) with the Nucleus 8 Sound Processor (SNR-NR on) and Nucleus 7 Sound Processor (SNR-NR on)
To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor (Expander On) compared with the Nucleus 7 Sound Processor (SNR-NR off)	Paired difference in percentage CNC/NVA Words correct in quiet (50 dB SPL) with the Nucleus 8 Sound Processor (Expander on) and Nucleus 7 Sound Processor (SNR-NR off)
To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor with FF (Moderate) and the Nucleus 7 Sound Processor	Paired difference in percentage CNC/NVA Words correct in quiet (50 dB) with the Nucleus 8 Sound Processor FF (Moderate) and Nucleus 7 Sound Processor

To characterise adult cochlear implant speech perception in co-located speech and noise (S0N0) with the Nucleus 8 Sound Processor with ForwardFocus ON (BEAM) compared with the Nucleus 7 Sound Processor with ForwardFocus ON (commercial version)	Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (65 dB SPL S0N0 4TB).

3 SCHEDULE OF EVENTS

	Screening[a]	Visit 1	Visit 2	Repeat Visit [c]
Written informed consent	X			
Demographics	X			
Eligibility	X			
Hearing history	X			
Device history	X			
Medical history	X			
SP fitting and optimisation		X	X	X
Sound Quality Assessment [b]		X	X	X
Speech perception testing – Words in Quiet		X		X
Speech perception testing – Sentences in Noise (S0N0)			X	X
Speech perception testing – Sentences in Noise (S0N90)			X	X
Concomitant medications/therapies		X		
Adverse Events		X	X	X
Device Deficiencies		X	X	X

	Screening[a]	Visit 1	Visit 2	Repeat Visit [c]
Device exposure		X	X	X

[a] *The screening visit can be combined with visit 1.*

[b] *Optional test.*

[c] *Repeat test if required. See section 7.3 for more details on the adaptive procedure that will be implemented if certain product issues are identified.*

4 BACKGROUND INFORMATION AND RATIONALE

4.1 Introduction

This clinical study aims to investigate the speech performance with the new Nucleus 8 Sound Processor (model: CP1110), compared with the commercially available Nucleus 7 Sound Processor (model: CP1000), with particular focus on the new microphones available with Nucleus 8 Sound Processor, and inclusion of the noise reduction feature ForwardFocus in the Automatic Scene Classifier 'SCAN'.

This study will build on the evidence collected in previous Nucleus 7 Sound Processor and ForwardFocus studies (see section 4.2.2),and will compare the performance across the Nucleus 8 and Nucleus 7 Sound Processors.

In this document, Nucleus 7 Sound Processor will be abbreviated to Nucleus 7 SP and will always refer to the sound processing unit model name CP1000, and Nucleus 8 Sound Processor will be abbreviated to Nucleus 8 SP and will always refer to the sound processing unit model name CP1110.

4.2 Findings of Previous Nonclinical and Clinical Studies

4.2.1 Nonclinical Data

Biological safety evaluation of the Nucleus 8 SP and accessories was conducted in compliance with:

- ISO / EN ISO 10993-1: October 2009 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- EN45502-2-3:2010 Active implantable medical devices Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems

Testing has confirmed that materials of the Nucleus 8 SP and accessories that are in contact with skin are biologically safe and suitable for use.

4.2.2 Clinical Data

Clinical data relevant for the current trial fall under two main categories 1) Evidence on previous Behind the Ear (BTE) SP generations and 2) Evidence on the development and approval of ForwardFocus. These clinical data are summarized below:

Behind the Ear Clinical Data

Most clinical evidence on the previously marketed BTE SP, Nucleus 7 SP is available from two Cochlear-sponsored clinical studies that have been carried out in Australia. These studies included some assessments very similar to those planned in the present study. These Cochlear sponsored studies and reports from published literature are summarized below:

Clinical Evaluation of Nucleus 7 Cochlear Implant System (CLTD5620)

The in-house study aimed to collect subjective impressions of the Nucleus 7 SP and associated accessories (CR310 and Nucleus Smart App) and to evaluate speech recognition performance of the Nucleus 7 SP in quiet and noise. A total of 46 subjects were enrolled in the study.

The Client Orientated Scale of Improvement (COSI) indicated a greater proportion of “benefit” vs. “no benefit” in eight of the nine categories covered by the responses. An additional custom questionnaire was devised to assess listening benefits provided by the CI system for specific aspects of hearing. Mean scores favoured the Nucleus 7 SP for all 27 questions, with significant differences for 11 questions. Cochlear implant specific quality of life (QoL) was measured via the Nijmegen questionnaire and for all three sub-domains (physical, psychological and social) there were significant improvements in QoL change greater than that expected by chance.

Mean speech recognition scores in quiet (CNC monosyllables) were not significantly different among the Nucleus 5, Nucleus 6, and Nucleus 7 SPs. The results of the adaptive sentences in noise test in the S_0N_0 condition showed that the mean speech recognition performance in noise with both the Nucleus 7 SP (SCAN) and Nucleus 6 SP (SCAN) was significantly better than with the Nucleus 5 SP (Zoom). In spatially separated noise, there were statistically significant performance differences between the Nucleus 5 SP (Zoom) and Nucleus 7 SP (SCAN). Overall, the speech recognition outcomes demonstrated equivalent performance for the Nucleus 7 SP (SCAN) and Nucleus 6 SP (SCAN) in both quiet and noisy test conditions.

The use of the Cochlear MiniMic 2+ and Phonak Roger 20 wireless microphones was compared with the Nucleus 7 SP SCAN baseline. Sentence recognition scores in both microphone conditions were significantly better than baseline. Performance with the MiniMic 2+ was significantly better than performance with the Roger 20 when speech was presented in noise.

Results of this study have been published[1].

ForwardFocus Clinical Data

Signal processing strategies are designed to remove some or all competing noise, while maintaining the target speech with little or no modification. The SNR-NR algorithm that was introduced in CP910/920 uses a single microphone or single channel input, is non-directional and performs best in steady-state background noise. The performance benefit is reduced in more modulated (non-stationary) noise such as when there are competing talkers (Dawson et al., 2011; Hersbach et al., 2012).

In contrast, ForwardFocus uses two fixed-directional microphones to capture spatial information, enabling noise to be filtered based on the location of the sound source. The signal of interest is defined as originating from in front of the listener and noise as originating behind or to the sides of the listener. If SNR-NR is enabled, it can operate on the output signal from ForwardFocus. The two noise reduction algorithms complement each other due to their different principles of operation. Hersbach et al. (2013) found that ForwardFocus provided a significant improvement in group mean speech reception threshold compared with BEAM.

A clinical evaluation of ForwardFocus performance (CRC5513), using the Nucleus 6 Sound Processor (Model CP910), revealed higher group mean speech perception scores with ForwardFocus (Zoom+Strong) than with Standard, Zoom or Beam(Z) (a modification of Beam that uses Zoom directionality) when speech was presented from the front of the listener and noise presented from the rear. Higher group mean speech recognition scores were also obtained with ForwardFocus compared to Standard and Zoom algorithms with speech presented from the front of the listener and speech weighted noise (SWN) from the rear. Group mean ratings for sound quality

ratings were higher with ForwardFocus than with Standard, Zoom or Beam(Z). There was no significant group difference in SSQ rating between ForwardFocus and the comparator programs (Standard, Zoom or Beam(Z)). There was an overall preference for “SCAN” with ForwardFocus over “SCAN” alone. The investigators concluded that ForwardFocus is most useful at improving speech intelligibility when the competing sources are to the sides and/or rear of the listener.

In study CRC5589/CTC5614, using the Nucleus 6 Sound Processor (Model CP910), speech perception outcomes and acceptance for three different strengths of ForwardFocus integrated with SCAN were compared with SCAN plus SNR-NR (N6 SCAN). Sentence recognition scores with noise in rear half noise was significantly better with all ForwardFocus programs than N6 SCAN. Word recognition scores in quiet and questionnaire ratings for all ForwardFocus programs were comparable to N6 SCAN. Sentence-in-noise scores obtained with speech and noise presented from the front were non-inferior to N6 SCAN for mild ForwardFocus only. A decrement compared with ForwardFocus Strong was found. Sentence in noise scores with speech presented to the cochlear implant side or from behind the listener with mild ForwardFocus were inferior to the baseline. Based on these findings the investigators recommended that ForwardFocus be introduced as a custom programme that could be selected for specific listening conditions.

Study CLTD5606 was designed to assess the effectiveness of ForwardFocus for speech reception in noise compared with the Nucleus 6 SCAN (SCAN + SNR-NR). The study included twenty-five conventional CI recipients. For sentence recognition with four-talker babble from the rear, all three levels of ForwardFocus (strong, medium and mild) were found to be superior to the Nucleus 6 SCAN. For speech-weighted noise presented behind the listener ForwardFocus Strong was demonstrated to be superior to the Nucleus 6 SCAN. When speech and either speech-weighted noise or four-taker babble were co-located in front of the listener, sentence recognition with ForwardFocus strong was similar to the Nucleus 6 SCAN. For CNC words in quiet ForwardFocus Strong was inferior to the Nucleus 6 SCAN. The investigators concluded that acceptable performance and safety of the ForwardFocus program can be anticipated for Nucleus 7 SP users in noisy environments, and the risk versus benefit profile is acceptable when ForwardFocus be used in quiet environments.

The in-house study CLTD5709 investigated the effect of ForwardFocus noise reduction on adult cochlear implant recipients’ speech perception scores, listening effort and subjective ratings using the Nucleus 7 SP. A total of 24 subjects were enrolled in the study.

Speech perception with babble noise from the rear demonstrated that ForwardFocus On was superior to ForwardFocus Off (Nucleus 7 default program SCAN). Listening effort as measured via a dual-task paradigm involving both speech perception and a visual reaction time task revealed no significant difference in reaction times between ForwardFocus On and ForwardFocus Off, and therefore no difference in listening effort.

Questions from the Speech domain of the ‘Speech, Spatial and Qualities of Hearing Scale’ (SSQ) and 3 questions from the Qualities of Hearing domain were completed by subjects at baseline and after at least 4 weeks of use with ForwardFocus. The mean Speech domain results collected after 4 weeks of use were not significantly different from baseline scores.

Subjective ratings on the custom questionnaires indicated strong satisfaction, ease of use, and confidence with ForwardFocus. The majority of respondents found the ForwardFocus controls within

the Nucleus Smart App as very easy to use and half of the respondents wanted ForwardFocus on their own processor.

4.3 Study Rationale

This study will build on the evidence previously collected on BTE sound processors and 'ForwardFocus', with particular focus on the speech perception performance of the Nucleus 8 SP in quiet, [redacted] and also whether the automation of ForwardFocus provides at least the same speech perception performance in quiet and noise when compared to the commercially available Nucleus 7 SP.

A more detailed description of the test conditions and rationale for their inclusion is available in Table 2.

To assess the primary and secondary speech perception objectives, the study incorporates a within-subject repeated-measures design in which each subject will undergo in-booth speech perception testing with all combinations of hardware and signal processing settings in a sound booth. The average difference scores will indicate the performance difference for each of the paired comparisons.

The speech perception testing will occur at two study visits, ensuring that all tests for a specific comparison are measured within the same test session to limit the influence of confounders such has tiredness, motivation, and attention.

5 MEDICAL DEVICE INFORMATION

5.1 Identity and Description of the Investigational Medical Device (IMD)

Nucleus 8 Sound Processor

The Nucleus 8 SP is a Behind-The-Ear sound processor to be used with a compatible Cochlear Implant and is manufactured by Cochlear Limited.

The minimum components required for normal operation of the Nucleus 8 SP are:

- CP1110 processing unit
- CP1110 Slimline coil,
- CP1110 Rechargeable Battery module
- CP1000 Magnets (approved devices)
- CP1000 Earhooks (approved device)

The Nucleus 8 SP incorporates the NEO-XS processor chip and C6 Hybrid chip, which allows for a smaller size sound processor, improved audio processing and improved support for GN ReSound Accessories when compared to previously marketed devices.

Figure 1: Image of the Nucleus 8 SP

The key component similarities compared with the previous generation (Nucleus 7) include swappable rechargeable or 2ZincAir batteries, an integrated coil and coil cable, a single push button, ForwardFocus which is an algorithm that reduces noise from behind and beside the listener while passing sounds from the front without attenuation. While not available for the current study, the product features intended for commercialisation also include three different receiver sizes for hybrid support, compatibility with True Wireless accessories, GN Resound hearing aids to enable bimodal operation and access to sound processor controls via the CR310 Remote Control and the Nucleus Smart App on compatible iOS and Android Phones.

The key component differences compared with the previous generation (Nucleus 7) include Bluetooth 5.2 Hearing Aid Profile (BTHAP) capable hardware (C6 Hybrid), and reduced size enabled by miniaturisation of components such as using Micro-Electro-Mechanical System (MEMS) microphones and C6 Hybrid chip. While not available for the current study, the commercial version will also include an adaptive ForwardFocus incorporated in the SCAN program if enabled by clinicians through the programming software (also known as “ForwardFocus in SCAN-X"), low energy audio streaming from mobile phones and BTHAP broadcasts and compatibility with next generation Cochlear Smart Implants.

The potential new adaptive “ForwardFocus in SCAN-X" feature will apply the ForwardFocus noise attenuation processing algorithm using different strengths in conjunction with the microphone directionality modes already used in SCAN (namely Standard, Zoom and Beam directionality modes). The commercial feature will, similarly to a SCAN program, automate switching between these ForwardFocus enabled configurations based on the Sound Class identified by the SCAN Sound Class classifier, which may make it possible for a recipient to have ForwardFocus always on when using SCAN. For the current study, using System Release version 2.1, the ForwardFocus enabled Standard, Zoom and Beam directionality modes will be available as non-automated (i.e., fixed) programs.

SCAN-X is an improvement to the SCAN automation system. Like SCAN, it switches directional processing modes based on an environmental classifier, that predicts whether the recipient is in a Quiet, Speech, Speech in Noise, Noise or Music environment from the microphone signal. The underlying environmental classifier in SCAN-X does additional analysis on the spectrum of the signal to improve its prediction accuracy.

[redacted]

For the current study, the Nucleus 8 SP will only be controlled by the button on the sound processor. The proposed commercial version of CP1110 will be controlled by either the Nucleus Smart App (on iOS or Android), the MFi Control (on the iPhone, iPad or iPod Touch), the Remote Control (CR310) or the button on the sound processor. Recipients can monitor the sound processor using the Android or iPhone Nucleus Smart App. Clinicians can program the Nucleus 8 SP with Custom Sound Pro (7.0), and for the current study the Cochlear Device Interface (CDI) tool will be used to load the study programs.

CDI is a layer between the fitting application and the Cochlear hardware systems (i.e., remote control, sound processor, implant, programming interface such as Custom Sound Pro). The CDI driver acts as a server to the client applications and offers a (software) framework for programming the Nucleus cochlear implant system in a uniform way while providing run-time services. A screenshot of the CDI software is shown in Figure 2.

Figure 2: Screenshot of Cochlear Device Interface (CDI)

The materials in contact with skin include:

- Sound processor and Battery casing: Co-polyester Tritan MX731
- Coil overmould and strain relief overmould: TPE 27A70
- Coil cable sheath Totoku PVC
- Magnet casing: ABS Colorcomp HMG94MDC
- Earhook – hard part: Polyamide Grilamid TR90 Clear
- Earhook – soft part: Silicone ShinEtsu KE 2090/70

Experienced Audiologists will fit the study device using the above-mentioned software. Any necessary training will be provided before study start.

Study subjects will be exposed to the device during testing sessions at the study site and will return to their own device in between test sessions and at the end of the study.

Intended Use

The Nucleus 8 Processing Units are intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The processing unit converts sounds into electrical signals, which it sends, via a coil, to an implant. The processing unit also provides power to the implant.

When used in combination with an audio receiver, the sound processor also delivers sound to the ear canal in recipients with residual hearing.

Intended Population

The Nucleus 8 SP is intended for patients implanted with a compatible Cochlear™ Nucleus® implant. There are no restrictions for the intended patient population of the Nucleus 8 SP in terms of age, weight, health or other condition.

All medical devices used in this investigation are manufactured by Cochlear Limited.

The IMD and/or the packaging for the device will state that the device is exclusively for use in a clinical investigation.

5.2 Identity and Description of the Comparator

For the purpose of speech perception testing, there is one comparator device; Nucleus 7 SP. Subjects will be exposed to the devices during two test periods, of up to three hours duration, at the study site. The Nucleus 7 SP, either loaned or the subjects' own device will be used during in the in-booth test sessions.

Nucleus 7

Nucleus 7 is a sound processor system manufactured by Cochlear Limited. The Nucleus 7 SP is commercially available. The sound processor is controlled by either the Nucleus Smart App (on iOS or Android), the MFi Control (on the iPhone, iPad or iPod Touch), the Remote Control (CR310) or the button on the sound processor. Recipients can monitor the sound processor using the Android or iPhone Nucleus Smart App. Clinicians can program the Nucleus 7 SP with Custom Sound Pro (6 or later).

The Nucleus 7 SP incorporate the NEO-XS new processor chip, which allows for a smaller size sound processor, lower power usage, improved audio processing and improved support for GN ReSound Accessories when compared to previously marketed devices.

Figure 3: Image of the Nucleus 7 SP (Model: CP1000)

The key component differences compared with the previous generation (Nucleus 6) include an integrated coil and coil cable, a single push button instead of two buttons used in the N6 sound processor, three different receiver sizes for hybrid support, compatibility with GN Resound hearing aids to enable bimodal operation via MFi, the introduction of ForwardFocus, and access to sound processor controls via the Nucleus Smart App on compatible Apple and Android Phones.

Table 1 compares the Nucleus 7 and Nucleus 8 SP variants in terms of signal processing technology, size, and connectivity.

Table 1 Nucleus 7 and Nucleus 8 SP Feature Comparison. Asterisks (*) denote features that will not be available with the Nucleus 8 SP for the trial.

Product Name	**Nucleus 7 SP**	**Nucleus 8 SP**
Model Number	**CP1000**	**CP1110**
		
[redacted]		
Dimensions (Processing unit+Standard Rechargeable Battery+medium earhook) **volume** **length** **height**	6.5 cm^3 44.98 mm 43.11 mm	6.0 cm^3 41.9 mm 43 mm
Weight	10.16 g (with 2ZnAir batteries) 9.83 g (with Standard Rechargeable battery) 7.95 g (with Compact Rechargeable battery)	9.5g (with Power Extend Rechargeable battery) [redacted] 7.0g (with Compact Rechargeable battery)
Colour range	5 colours and 2 detail options	6*

Direct Streaming Choice	Android iPhone	Android* iPhone* Bluetooth 5.2 Hearing Aid Profile*
Wireless Accessory support	Prox 2	Prox 2*
Input Processing Technologies	BEAM SNR-NR WNR FF with Zoom Whisper SCAN	BEAM SNR-NR WNR* FF with standard FF with Zoom FF with BEAM Whisper* SCAN X*
Core Control: Processor, CR310*, Nucleus Smart App*.		
Core Connected Care: Remote Check*-ready, CS Pro programming software		

Table 2 Speech perception comparisons and rationale

Test condition	Comparison	Rationale
CNC/NVA words in Quiet (50 dB SPL)	Treatment: Nucleus 8 standard directionality SNR-NR on Control: Nucleus 7 standard directionality SNR-NR on	[redacted]
	Treatment: Nucleus 8 standard directionality SNR-NR off [redacted] Control: Nucleus 7 standard directionality SNR-NR off	
	Treatment: Nucleus 8 standard directionality FF (Moderate) Control: Nucleus 7 standard directionality	Previous evidence with ForwardFocus (FF) in quiet has shown a small decrease in performance in quiet (5% at 50 dB SPL) with a 'Strong' attenuation setting (CLTD5606). It is predicted that ForwardFocus with a Moderate maximum attenuation setting will produce a non-inferior result when compared with Nucleus 7 for words in quiet (S0).
Sentences in noise S0N0 4-talker babble (65 dB SPL)	Treatment: Nucleus 8 BEAM directionality + FF (GT0, Strong)	Previous evidence with FF in S0N0 has shown: • A decrement compared to Nucleus 6 SCAN when FF was coupled with BEAM (GT3) (CRC5589)

Test condition	Comparison	Rationale
	Control: Nucleus 7 Zoom directionality + FF (GT0, Strong)	• A non-inferior result compared to Nucleus 6 SCAN when FF was coupled with Zoom (GT0) (CLTD5606) • A benefit compared to Nucleus 6 BEAM when FF was coupled with BEAM (GT3) (unpublished Kiel data) The combination of GT0+BEAM with ForwardFocus is predicted to resolve this performance issue.
Sentences in noise S0N90 4-talker babble (65 dB SPL)	Treatment: Nucleus 8 BEAM directionality +FF (GT0, Strong) Control: Nucleus 7 Zoom directionality + FF (GT0, Strong)	Previous evidence with BEAM in S0N+/-90 showed a significant speech perception improvement over Zoom when measured in non-fluctuating speech-spectrum shaped noise [2]. There is no known published evidence with FF in S0N90 however a significant improvement is expected over commercially available settings due the ability of the adaptive beamformer to steer the null to more locations than the fixed directionality Zoom, as currently implemented with Nucleus 7. The Cochlear Sponsored study CLTD5709 showed a 1.07 dB SRT improvement with BEAM over Zoom + FF, it is anticipated that BEAM+FF will further improve this benefit.

5.3 Accessory Device Requirements

The Nucleus 8 SP must be used together with an implanted receiver-stimulator to achieve normal operation in clinical use.

To utilise the sound processor system, in addition to the processing unit, recipients will also use a compatible ear hook, battery module, coil, and magnet.

The Nucleus 8 SP is compatible with the Cochlear™ Wired Programming Pod.

All study sound processors will be compatible with the Custom Sound Pro fitting software. This software will be used by the investigator to program the sound processors.

The research configurations of FF for N8 SP will be programmed via CDI-Tool.

6 OBJECTIVES

6.1 Primary Objective

To characterise adult cochlear implant speech perception in spatially separated speech and noise (S0N90) with the Nucleus 8 SP with ForwardFocus ON (BEAM) compared with the Nucleus 7 Sound Processor with ForwardFocus ON (commercial version)

6.2 Secondary Objective

- To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor (SNR-NR on) compared with the Nucleus 7 Sound Processor (SNR-NR on)
- To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor [redacted]) compared with the Nucleus 7 Sound Processor (SNR-NR off)
- To characterise adult cochlear implant speech perception in quiet with the Nucleus 8 Sound Processor with FF (Moderate) and the Nucleus 7 Sound Processor
- To characterise adult cochlear implant speech perception in co-located speech and noise (S0N0) with the Nucleus 8 Sound Processor with ForwardFocus ON (BEAM) compared with the Nucleus 7 Sound Processor with ForwardFocus ON (commercial version)

6.3 Exploratory Objective

There are no exploratory objectives.

7 DESIGN OF THE CLINICAL INVESTIGATION

7.1 General

This is a pivotal, prospective, pre-market, multi-site, non-randomised, open-label, within-subject, repeated-measures clinical investigation in adults with sensorineural hearing impairment who are current users of a Nucleus Cochlear Implant system.

See section 21 for description of subject population.

After enrolment, subjects will attend scheduled study visits over a two months study period as described in the CIP Schedule of Events (Section 3). At study visits, subjects will undergo hearing assessments. Safety will be assessed by recording and summarising all Adverse Events (AE)/

Adverse Device Effects (ADE) and Device Deficiencies (DD). No data monitoring committee will be used for this clinical investigation.

7.1.1 Design Rationale

Experienced adult cochlear implant recipients have been chosen as the study population due to their ability to compare sound processors across generations, in and outside of the booth. In addition, performance benefits achieved by adults can generally be extrapolated to younger age groups, avoiding the need to recruit this vulnerable population.

Comparison will be made within-subject with repeated measures for each of the sound processing conditions to be evaluated. There will be two test sessions with no take home use between sessions. The test sessions will include speech perception tests including sentence in noise and words in quiet tests. These speech measures are routine outcome measures used to evaluate new signal processing algorithms and hardware.

There will be no blinding of the study investigators.

Blinding of the study subject will be undertaken where possible, particularly when multiple signal processing conditions are loaded onto a single study device. Patients will not be told which program will be used in which order, and due to the similar form factor of the SP generations, it may also be possible to conceal which SP is being used during testing.

Counter-balancing of the test order will be undertaken where possible to limit the influence of order effects on results.

7.2 Subjects

The subjects include men and women aged 18 years or older who are current users of a Nucleus 6 (CP910/920), Kanso (CP950) or Nucleus 7 (CP1000) Sound Processor. Subjects will be screened, and 20 eligible subjects will be recruited in the clinical investigation. For speech perception testing, all subjects will receive all treatment and control conditions; however, the test order will be counterbalanced/ randomised to control for order effects.

Written, informed consent must be obtained from the subject before any study procedures are initiated.

7.2.1 Inclusion Criteria

Subjects must meet all of the inclusion criteria described below to be eligible for this clinical investigation.

1) Aged 18 years or older
2) Post lingually deafened
3) Implanted with the CI600 Series (CI612, CI632, CI622, CI624), CI500 Series (CI512, CI532, CI522) or Freedom Series (CI24RE(CA), CI24RE(ST), CI422)
4) At least 6 months experience with a cochlear implant.
5) At least 3 months experience with a Nucleus 6 (CP910/920), Kanso (CP950), Kanso 2 (CP1150) or Nucleus 7 (CP1000) Sound Processor
6) Able to score 30% or more at +15 SNR with CI alone on a sentence in babble test

7) Willingness to participate in and to comply with all requirements of the protocol.
8) Fluent speaker in language used to measure speech perception Willing and able to provide written informed consent

7.2.2 Exclusion Criteria

Subjects who meet any of the exclusion criteria described below will not be eligible for this clinical investigation.

1) Additional disabilities that would prevent participation in evaluations.
2) Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedures.
3) Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator.
4) Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling.
5) Cochlear employees or employees of Contract Research Organisations or contractors engaged by Cochlear for the purposes of this investigation.
6) Currently participating, or participated in another interventional clinical study/trial in the past 30 days, or (if less than 30 days) the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation.

7.2.3 Number of Subjects Required

See Section 9.4 Sample size considerations

7.2.4 Vulnerable Populations

Pregnant women may be recruited into the research project without in any way being targeted by virtue of their being present in the general population from which the participants are being recruited. The study procedures including the investigational devices will have no impact on the health and safety of this population.

7.2.5 Recruitment and Study Duration

The following subject status definitions apply:

- Enrolled: A subject that has signed the Informed Consent form for the study.
- Screen Fail: An Enrolled subject that has been determined to not meet one or more eligibility criteria.
- Participated: Subjects who have met eligibility criteria and have commenced baseline assessments.
- Withdrawn: An Enrolled subject who withdrew or was withdrawn by the Investigator or Sponsor before the expected End of Study visit. Withdrawn subjects may still continue in safety follow up until their scheduled End of Study visit, for reasons described in section 7.2.6.
- Completed: Enrolled subjects who have completed the required treatment and visit schedule.

The recruitment period for the clinical investigation is estimated to be 1 month from the time of first subject consent to recruitment of the last subject.

The expected duration of each subject's participation in the clinical investigation, is 2 months from the time of informed consent through to the last study visit.

Clinical Investigation completion is last subject last visit. In the event of an ongoing SAEs/SADEs at the time of this last visit, the clinical investigation completion will be extended for a further 30 days, or until resolution or stabilisation of the event, whichever comes first.

7.2.6 Criteria for Subject Withdrawal

Subjects can decide to withdraw from the investigation at any time. The Investigator shall ask the reason(s), however, subjects have the right to withhold their reason if preferred. The reason for withdrawal should be documented in the subject's source files and the case report form (CRF).

The Investigator or Sponsor may also decide to withdraw a subject from the clinical investigation if it is considered to be in the subject's best interests.

Subject withdrawal may be for any of the following reasons:

- Adverse Event (AE)
- Device Deficiency (DD)
- CIP or GCP deviation
- Subject withdrew consent
- Subject lost to follow-up
- Subject death
- Sponsor decision
- Investigator decision

If a subject is lost to follow-up, every possible effort must be made by the study site personnel to contact the subject and determine the reason for discontinuation. At least 3 separate attempts taken to contact the subject must be documented.

Participating subjects who are withdrawn/discontinued will not be replaced.

7.2.7 Randomisation Procedures

Subjects will not be randomised to a treatment condition. To control for order effects, counterbalancing of the test order will be implemented for the primary and secondary speech perception endpoints. All permutations will be represented evenly across the subjects where possible.

7.2.7.1 Blinding Procedures

For in booth speech perception testing, the test order will not be revealed to the study subject. The counterbalancing as outlined in Section 7.2.7 will be used to ensure that there is a balanced order of test conditions.

7.2.8 Post-investigation Medical Care

All IMD management during the study will be done by the study investigators. Subjects will be able to see their regular clinicians when wearing their own sound processors. At the end of each test session, subjects will return all investigational devices to the investigator and return to using their own sound processors programmed with commercial programming software versions. Subjects will continue to be clinically managed by their regular clinician according to their clinic's standard practice after the clinical investigation has been completed.

7.3 Performance Evaluations and Procedures

For Belgium: As mentioned in section 4.3, this is a multi-center investigation. The investigator of the clinic is responsible for subject recruitment, obtaining Informed Consent, assessment of inclusion- and exclusion criteria and assessment of hearing and medical history related to the Clinical Investigation Plan. Subjects are then referred to the investigator of CTC and will be evaluated as per the investigational procedures in the facilities of CTC.

Speech perception in quiet

Speech perception in quiet will be measured using the CNC monosyllabic words[3] at Australian sites and Nederlandse Vereniging Audiologie (NVA) words[4] at Belgian sites at 50 dB SPL from S0 position. See Figure 2. There will be 2 lists (CNC) or 3 lists (NVA) per condition (see Table 3 for input processing conditions). The goal of speech perception assessment in quiet is to compare % words correct for each of the conditions.

The CNC word test consists of 30 lists each with 50 words per list, recorded in a female voice. The NVA word test consists of 15 lists, each with 1 practice word and 11 test words per list, recorded in male voice.

Speech perception in noise

Speech perception in noise will be measured using the Australian Speech Test In Noise (AuSTIN)[5], which is a test that uses BKB like target sentences presented in adaptive noise in Australia, and the Leuven Intelligibility Sentences Test (LIST) in Belgium[6]. The signal level will be fixed at 65 dB SPL and each subject will be tested with 2 lists (AuSTIN) or 3 lists (LIST) per condition.

The AuSTIN corpus comprises 80 lists of 20 sentences each, recorded in female voice[5]. The LIST corpus comprises 35 lists of 10 sentences each, recorded in female and 38 lists of 10 sentences each, recorded in male voice [4,6]. The goal of the adaptive Speech-in-Noise testis to obtain the Speech Reception Threshold (SRT) in noise. We define the Speech Reception Threshold (SRT) as the Signal to Noise Ratio (SNR) in decibels at which a patient can understand 50% of the keywords in the sentences.

Speech perception performance in noise and quiet will be assessed using a loudspeaker configuration as shown in the diagrams of Figure 4.

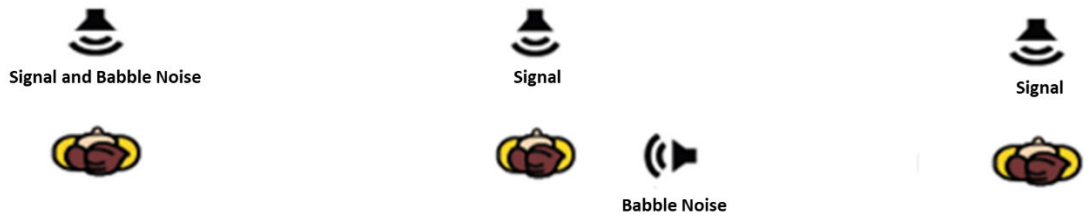


Figure 4. Left – S0N0 with signal and 4 talker babble from 0 degrees azimuth (in front), Middle – S0N90 with 4 talker babble at the test ear and signal from the front and Right – S0 CNC/NVA words from the front

Sound Quality

Subjective sound quality assessment with the investigational sound processor may occur before or after the acute speech perception assessment. Handwritten notes will be stored in the subject file and all device deficiencies will be stored in the electronic data base (Medidata Rave). These assessments may be undertaken in real world environments around the study site.

Participant Evaluations and Procedures

Screening Visit and Visit 1 (may be combined)

Included in this period:

- Screening and informed consent
- SP fitting
- Sound Quality
- Speech perception in quiet testing

Screening and informed consent:

- Subjects will be enrolled
- Subjects must be consented to the study and inclusion and exclusion criteria confirmed prior to any study activities starting.

SP Fitting and Optimisation

Prior to assessing speech perception in quiet, the test sound processors will be loaded according to the input processing settings identified in Table 3.

ADRO is the adaptive dynamic range optimisation processing setting, and ASC is the auto sensitivity processing setting, both of which will be enabled or disabled in the test sound processors according to each subject's preferred settings on their own MAP; if the study subject uses and prefers ADRO and ASC in their own Sound Processor, then these setting will be enabled in the study sound processor.

SNR-NR is a single channel noise reduction algorithm and directionality refers to the microphone directionality that will be enabled. These signal processing settings will be enabled/disabled via the fitting software CDI Tool and Custom Sound Pro (see Appendix 2)

Sound Quality

Study investigators will ask study subjects to use the investigational medical device in settings around the study site. Study investigators may ask the study participants questions about the sound quality and general acceptance of the Nucleus 8 (CP1110) Sound Processor system. This informal sound quality assessment may occur before or after the acute speech perception assessment, handwritten notes will be stored in the subject file and all device deficiencies will be stored in the electronic data base (Medidata Rave).

Words in quiet test

In booth speech perception testing will be conducted using the input processing combinations and hardware listed in Table 3. The order of testing will be conducted according to the counterbalancing outlined in Section 7.2.7.

Table 3. Speech in Quiet test conditions. NB Whisper and WNR will be off, ADRO and ASC will be on per user preference.

	Expander	SNR-NR	Directionality	ForwardFocus
Nucleus 8 Expander	✓		Std	
Nucleus 7 SNR-off			Std	
Nucleus 8 SNR on		✓	Std	
Nucleus 7 SNR-on		✓	Std	
Nucleus 8 std FF		✓	Std	✓(Moderate)

All subjects will be tested in the unilateral condition and each subject will have their contralateral ear (non-test ear) blocked with an EAR plug for all test conditions. Subjects with bilateral implants that meet the inclusion criteria will be tested using the subject's preferred ear or if the preferred ear is not known then the first implanted ear will be used as the test-ear.

The subject will be positioned so that the middle-point of two ears is centred at the reference point of the sound field. The loudspeaker should be positioned at the same height as the middle-point of the two ears.

The test material will be presented via software on a PC or laptop. The investigator, or suitably qualified delegate will use the software to select:

- CNC/NVA word test
- 50 dB SPL presentation level
- Signal from in front (0 degrees)
- 2 lists (CNC) or 3 lists (NVA) per condition

At the end of each run, the investigator will record the result on the worksheet and in the EDC.

End of visit and return of study devices

After the speech perception evaluation has been completed, study subjects will return the study devices and will use their own device as normal in their home environment in between speech evaluation study visits.

Visit 2

Included in this visit:

- SP fitting and optimisation
- Sound Quality

- Speech in noise testing (S0N0 and S0N90)
- Return devices and study completion

Table 4. Speech in Noise test conditions (S0N0 and S0N90). NB Whisper and WNR will be off, ADRO and ASC will be on per user preference.

	Gain Threshold	SNR-NR	Directionality	ForwardFocus
Nucleus 8 FF+BEAM	0	✓	BEAM	✓ (Strong)
Nucleus 7 FF	0	✓	Zoom	✓ (Strong)

Sentence in noise test (S0N0)

In booth speech perception testing will be conducted using the signal processing combinations and hardware listed in Table 4. The order of testing will be conducted according to the counterbalancing outlined in Section 7.2.7.

For S0N0 and S0N90 speech in noise tests, all subjects will be tested in the unilateral condition and each subject will have their contralateral ear (non-test ear) blocked with an ear plug for all test conditions.

The subject will be positioned so that the middle-point of two ears is centred at the reference point of the sound field. The loudspeaker should be positioned at the same height as the middle-point of the two ears.

The test material will be presented via software on a PC or laptop . The investigator, or suitably qualified delegate will use the software to select:

- Adaptive test (SRT)
- 65 dB SPL presentation level
- Signal from in front (0 degrees)
- Babble noise from in front (0 degrees)
- 2 lists (AuSTIN) or 3 lists (LIST)

At the beginning of the test session a practice run with the first signal processing combination to be tested will be undertaken. This practice run is not required to be repeated if all sentence tests are completed on the same day. The starting point for the first test will be set within 5dB SNR of the practice run result. The number of sentences will be 20 (AuSTIN) or 10 (LIST) for all test runs.

At the end of each run, the investigator will record the result on the worksheet and in the Electronic Data Capture (EDC) system.

Sentence in noise test (S0N90)

In booth speech perception testing will be conducted using the signal processing combinations and hardware listed in Table 4. The order of testing will be conducted according to the counterbalanced table in Section 7.2.7.

The subject will be positioned as per the S0N0 testing outlined above.

The test material will be presented via software on a PC or laptop . The investigator, or suitably qualified delegate will use the software to select:

- Adaptive test (SRT)
- 65 dB SPL presentation level
- Signal from in front (0 degrees)
- Four taker babble noise from the side of the test ear (90 or 270 degrees)
- 2 lists (AuSTIN) or 3 lists (LIST)

At the end of each run, the investigator will record the result on the worksheet and in the Electronic Data Capture (EDC) system.

Return devices and study completion

At the end of the study, subjects will return to their own device with the commercially available firmware.

Adaptive procedure:

While there are no expected unplanned product changes, early product can be sensitive to the low-risk issues identified in

Table 5. During this feasibility study these product issues may be identified by study subjects during the acute testing sessions that require optimisation or correction, and an adaptive procedure allows for product feedback to be collected from study subjects, for the product to be updated, and for the updated product to be reissued to study subjects for continued testing. Table 1 identifies how issues will be investigated and retested by the research subjects.

Before initiating speech perception testing, study investigators may ask study subjects to use the investigational medical device in settings around the study site. As identified in the visit 1 procedures.

New Device Iteration:

If a product issue is identified either prior to or during the speech perception evaluation that may have an impact on speech perception outcomes, the study will be paused for all subjects while the change is made and a new version of the Sound Processor system will be developed and issued to study participants.

If the product issue was present for all subjects, then all subjects will be asked to repeat any testing that had occurred.

Table 5. Product adaptation categories and product issue examples

Category	Example of a product issue	Action
Sound quality	Study subjects may provide feedback on the general sound quality of the Sound Processor in everyday sound environments like noisy cafes, quiet rooms or windy situations.	If the issue has an impact on performance the product will be updated and speech perception will be re-evaluated by subjects.
	Study subjects may provide feedback that the Sound Processor is unacceptably noisy or has an unacceptably noticeable buzzing.	If the issue has an impact on performance the product will be updated and speech perception will be re-evaluated by subjects.
Intermittency	Study subjects may provide feedback that the Sound Processor is not outputting a consistent signal with gaps in stimulation.	If the issue has an impact on performance the product will be updated and speech perception will be re-evaluated by subjects.
General bugs and product issues:	While all measures have been undertaken to test each of the features with the Nucleus 8 (CP1110) Sound Processor, there may be unforeseen issues that are exposed through usage in the environments used in the study.	General issues will be judged on a case by case basis. If it is judged that the issue has an unacceptable impact on performance, the product will be updated and re-evaluated by subjects.

All product issues will be recorded as device deficiencies. The Sound Processor will be considered mature for speech perception testing when all product optimisations that impact on performance have been made.

Multiplicity and Type I error

This adaptive procedure will only be incorporated when subjective issues are raised by study subjects, and will not be based on the speech perception scores collected during the session.

No repetition of speech perception will occur after the database has been locked. As such, no control of Type I error is necessary when sound quality or intermittencies are identified during data collection.

7.4 Safety Evaluations and Procedures

The risks and anticipated ADEs for the Nucleus 8 SP, as identified in Sections 8.2 and 8.3 of the CIP, will be assessed in the clinical investigation via reporting of all AEs/ADEs from the time of first subject first visit until last subject last visit.

Safety data adjudication may be conducted by the Sponsor's Medical Officer in accordance with the Sponsor's standard operating procedures.

7.4.1 Concomitant Medication and Therapies

There is potential that concomitant medical treatments may influence the outcomes of this study. All concomitant medical treatments will be collected as part of this study.

7.5 Equipment Used for Evaluation of Performance and Safety

7.5.1 Speech Perception

Speech perception performance in quiet will be assessed using a loudspeaker configuration with the speech from the front (S0).

Speech perception performance in noise will be assessed using a loudspeaker configuration with the speech and noise from the front (S0N0) and with speech from in front and noise to the side of the test ear (S0N90).

The loudspeakers will be located at head height for a seated subject (reference point). The distance from the loudspeaker from the reference point will be approximately one meter. There will be defined locations for the loudspeakers and subject within the test environment.

7.6 Sponsor Role in Conduct of the Clinical Investigation

Sponsor and investigator roles are assumed by Cochlear employees.

Cochlear has designed and will execute this clinical trial in-house at Cochlear Limited, Sydney, at Cochlear Limited, Melbourne and at the Cochlear Technology Centre (CTC) in Mechelen, Belgium. The study sites consist of a small team of Investigators, trained as clinical Audiologists, to execute this research activity. Investigators are qualified audiologists familiar with cochlear implant development, surgery and programming. Investigators' trial materials and testing rooms (sound booths) are securely separated from Sponsor facilities. The trial investigators, or delegates within the study site, will enter the data into the eCRF.

The study is planned, designed and developed by a separate group within Cochlear, known as Clinical Affairs (the Sponsor). Cochlear has SOPs to manage the separation of Investigator and Sponsor activities as well as ensure they align with all applicable regulations.

8 RISKS AND BENEFITS OF THE INVESTIGATIONAL MEDICAL DEVICE AND CLINICAL INVESTIGATION

8.1 Anticipated Clinical Benefits

Study subjects will be asked to use hearing performance features associated with the Nucleus 7 and Nucleus 8 SPs during acute testing sessions, however this is not anticipated to provide benefits to the subject due to the acute nature of the testing.

Subjects who haven't previously experienced using the ForwardFocus feature may experience benefit of improved communication through reduction of distracting noise while using the feature during the session only.

Due to the limited use of the investigational devices, there are no long-term clinical benefits anticipated for the study subjects.

8.2 Anticipated Adverse Device Effects

Cochlear's internal hazards analysis considers probable hazardous situations relating to the Nucleus 7 and Nucleus 8 SPs.

The risks associated with the Nucleus 7 and Nucleus 8 SPs and Accessories have been identified, analysed and evaluated. The residual risk level has been determined to be as low as possible in accordance with Cochlear's Product Risk Management Procedure and are acceptable.

Subjects may be exposed to the anticipated adverse device related effects associated with use of the Nucleus 7 and Nucleus 8 SPs such as pain or discomfort when wearing the processor and a risk that some sounds could be uncomfortable. Product specific warnings can be found in the respective User Guide and relevant instructions for use.

8.3 Risks Associated with Participation in the Clinical Investigation

There is a small risk that programs on the Nucleus 7 and Nucleus 8 SPs may sound different to each user's own sound processor; this is unlikely if study subjects enter the study already using a Nucleus 7 Sound processor and more likely if they enter a study with a legacy device or an off-the-ear sound processor. If subjects experience sound that is uncomfortable, they are counselled to remove the sound processor off their head or ask the research audiologist to immediately cease stimulation. Other risks may include exacerbation of existing tinnitus and a reduction in the sound quality or intelligibility of the research programs. Subjects are advised to return to their own processor and promptly inform the investigators if these events occur.

Warnings and contraindications

See the Nucleus 7 SP User Guide for all Warnings and Contraindications. (user guides can be found within the 'Support' section of the country specific Cochlear website; www.cochlear.com). AT this preliminary stage in development, the Nucleus 7 SP User Guide will be relevant for Nucleus 8 SP.

8.4 Risk Mitigation

The study investigational devices have been fully tested for safety, and the performance and use of the investigational devices is expected to be similar to the approved Nucleus 7 SP. Risks have been individually reviewed and found to be clinically acceptable based on implemented controls, verification activities, and the relatively low probability of harm. One or more of the following risk control options are applied to each identified risk: inherent safety by design; protective measures in the device itself or in the manufacturing process; Information for safe usage; investigational procedures.

The residual risks related to the investigational device or procedure will be controlled in the following ways:

- The fitting and use of the Nucleus 8 SP will conducted by a trained audiologist. Test units will be used for a short duration (up to 3 hours) and will be used by adults who are able to indicate discomfort and remove the sound processor from their head.
- If recipients experience any physical discomfort from the device or if the device produces sounds that are uncomfortable, subjects are encouraged to inform the Investigator and return to using their own sound processor.
- Dropped devices should be inspected for external damage before re-use, to ensure there are no sharp edges/corners or rough surfaces.

8.5 Risk-to-Benefit Rationale

The Nucleus 8 Hazards Analysis indicates that the risk portion of the benefit-risk profile of the Nucleus 8 System is acceptable when used as intended by the intended users. The safety, performance, and patient benefits of the Nucleus 8 System are designed to be at least comparable to the approved Nucleus 7 SP and therefore in line with those expected based on the state of the art for the therapy.

9 STATISTICAL CONSIDERATIONS

9.1 General Considerations

See sections 9.2 to 9.10 for statistical considerations.

9.2 Endpoints

For speech in noise (AuSTIN/LIST) endpoints, two (AuSTIN) or 3 (LIST) lists of sentences will be measured per sound processor condition, and the two dB SRT values will be averaged to produce a single value per condition, per subject.

For speech in quiet (CNC/NVA) endpoints, two (CNC) or three (NVA) lists of words will be measured per sound processor condition, and the two percentage words correct values will be averaged to produce a single value per condition, per subject.

9.2.1 Primary Endpoint

The primary efficacy measure for the Nucleus 8 Sound processor will be Speech Reception Thresholds (SRT) assessed via AuSTIN/LIST Sentence scores in spatially separated adaptive noise.

The primary efficacy outcome for the study will be determined by the following primary efficacy endpoint:

- Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (S0N90 4TB).

9.2.2 Secondary Endpoints

Secondary efficacy measures will be the percentage words correct as assessed by CNC, NVA Monosyllabic word scores in quiet.

Secondary efficacy outcomes for will be determined by the following endpoints:

- Paired difference in percentage CNC/NVA Words correct in quiet (50 dB) with the Nucleus 8 Sound Processor (SNR-NR on) and Nucleus 7 Sound Processor (SNR-NR on)
- Paired difference in percentage CNC/NVA Words correct in quiet (50 dB) with the Nucleus 8 Sound Processor [redacted] and Nucleus 7 Sound Processor (SNR-NR off)
- Paired difference in percentage CNC/NVA Words correct in quiet with the Nucleus 8 Sound Processor (Moderate) and Nucleus 7 Sound Processor (Standard directionality)

An additional secondary efficacy measure will be Speech Reception Thresholds (SRT) assessed via AuSTIN Sentence scores in spatially separated adaptive noise according to the following endpoint:

- Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (S0N0 4TB).

9.2.3 Exploratory Endpoints

There are no exploratory endpoints

9.3 Hypotheses

For the non-inferiority test of SRT sentences for both primary and secondary endpoints, the 95% CI (alpha=0.025 one-sided) for the mean paired difference (i.e., 'Nucleus 8 SP' versus 'Nucleus 7 SP') will be calculated. If the upper limit of the 95% CI of the mean paired difference is lower than 1dB, the 'Nucleus 8 SP' is regarded as non-inferior to 'Nucleus 7 SP' on that measure.

For the non-inferiority test of CNC/NVA word score, the 95% CI (alpha=0.025 one-sided) for the mean paired difference (i.e., 'Nucleus 8 SP' versus 'Nucleus 7 SP') will be estimated. If the lower limit of the 95% CI of the mean paired difference is above -10%, 'Nucleus 8 SP' is regarded as non-inferior to 'Nucleus 7 SP' on that measure.

9.3.1 Primary Hypotheses

Endpoint: Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (S0N90 4TB).

H0: Sentence in noise (S0N90 4TB) scores (dB SRT) with the Nucleus 8 Sound Processor with FF On (treatment) are inferior to those with the Nucleus 7 Sound Processor with FF On (control)

Nucleus 8 FF ON – Nucleus 7 FF OFF ≥ 1 dB (NB: higher SRT scores represent poorer performance)

H1: Sentence in noise (S0N90 4TB) scores (dB SRT) with the Nucleus 8 Sound Processor with FF On (treatment) are non-inferior to those with the Nucleus 7 Sound Processor with FF On (control)

Nucleus 8 FF ON – Nucleus 7 FF OFF < 1 dB

9.3.2 Secondary Hypotheses

Secondary endpoint 1

Paired difference in percentage CNC/NVA Words correct in quiet (50 dB) with the Nucleus 8 Sound Processor (SNR-NR on) and Nucleus 7 Sound Processor (SNR-NR on)

H0: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor SNR-NR on (treatment) are inferior to those with the Nucleus 7 Sound Processor SNR-NR on (control)

Nucleus 7 SNR-NR ON – Nucleus 8 SNR-NR ON $\leq$ -10%

H1: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor SNR-NR on (treatment) are non-inferior to those with the Nucleus 7 Sound Processor SNR-NR on (control)

Nucleus 7 SNR-NR ON – Nucleus 8 SNR-NR ON > -10%

Secondary endpoint 2

Paired difference in percentage CNC/NVA Words correct in quiet (50 dB) with the Nucleus 8 Sound Processor [redacted] and Nucleus 7 Sound Processor (SNR-NR off)

H0: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor [redacted] (treatment) are inferior to those with the Nucleus 7 Sound Processor SNR-NR off (control)

Nucleus 7 SNR-NR Off – Nucleus 8 [redacted] ON $\leq$ -10%

H1: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor [redacted] (treatment) are non-inferior to those with the Nucleus 7 Sound Processor SNR-NR off (control)

Nucleus 7 SNR-NR Off – Nucleus 8 [redacted] ON > -10%

Secondary endpoint 3

Paired difference in percentage CNC/NVA Words correct in quiet with the Nucleus 8 Sound Processor (Moderate) and Nucleus 7 Sound Processor

H0: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor FF Moderate (treatment) are inferior to those with the Nucleus 7 Sound Processor std (control)

Nucleus 7 std – Nucleus 8 FF Moderate $\leq$ -10%

H1: Words in quiet (50 dB CNC/NVA words) scores (% words correct) with the Nucleus 8 Sound Processor FF Moderate (treatment) are non-inferior to those with the Nucleus 7 Sound Processor std (control)

Nucleus 7 std – Nucleus 8 FF Moderate > -10%

Secondary endpoint 4

Paired difference in dB SRT (AuSTIN/LIST) between the Nucleus 8 Sound Processor with ForwardFocus On (BEAM) and the Nucleus 7 Sound Processor with ForwardFocus On (commercial version) (S0N0 4TB).

H0: Sentence in noise (S0N0 4TB) scores (dB SRT) with the Nucleus 8 Sound Processor with FF On (treatment) are inferior to those with the Nucleus 7 Sound Processor with FF On (control)

Nucleus 8 FF ON – Nucleus 7 FF OFF ≥ 1 dB (NB: higher SRT scores represent poorer performance)

H1: Sentence in noise (S0N0 4TB) scores (dB SRT) with the Nucleus 8 Sound Processor with FF On (treatment) are non-inferior to those with the Nucleus 7 Sound Processor with FF On (control)

Nucleus 8 FF ON – Nucleus 7 FF OFF < 1 dB

9.3.3 Exploratory Hypothesis

There are no hypotheses for the exploratory endpoints

9.4 Sample Size Determination

This study is a non-inferiority design, and sample size calculation was based on non-inferiority tests for SRT (Speech Recognition Threshold) scores and CNC word scores. The sample size using a confidence interval method (one-tailed 97.5% confidence interval) was estimated to have a reasonable power to detect non-inferiority of sentence and word scores for the above-mentioned hypotheses.

To reject the null hypothesis of inferior sentence in noise scores (SRT scores), the following parameters for sample size calculation were chosen:

- A clinical important difference value of 1 dB SRT. This margin is based on clinical consensus. NB: *higher SRT scores represent poorer performance*.
- A standard deviation (SD) of change or difference scores of 1.36 dB. This SD is calculated from 256 paired differences and is an indicative test re-test SD for both S0N3 and S0N0.
- A significance level α = 0.025 (one-tailed).
- A desired power of 0.8

Based on these assumptions, a sample size of 17 are required to reject the null hypotheses. Twenty subjects will be enrolled to allow for any unforeseen subject withdrawal.

9.5 Analysis Populations

The analysis of the primary endpoint will be based on the Intent-To-Treat (ITT) and Per Protocol (PP) analysis populations in order to support a conclusion of non-inferiority. The inclusion of both ITT and PP populations has been chosen to assess the robustness of the study results and the consistency of the study measures under different analysis populations.

This study has a non-inferiority design; therefore, the primary analysis will be based on the PP population.

For cases in which the ITT and PP populations lead to the same conclusions and final interpretations about the treatment effect, the results will be considered to not be influenced by underlying factors such as missing data and protocol deviations, and the results would be considered to be robust and consistent under different analysis populations. A statement to reflect this will be included in the CIR.

For cases in which the ITT and PP populations lead to different final interpretations or conclusions, all of the results will be reported and the differences in outcomes will be identified and explored.

Intent-to-Treat Population

The Intent-to-Treat Population will include all subjects who receive the treatments and have at least one set of paired treatment and control measurements from any endpoint, regardless of protocol deviations and missing data.

Per Protocol Population

The Per Protocol Population will include all subjects who receive the treatments and have at least one paired measurement from treatment and control, without major protocol deviations. Major deviations will be defined at the clean file meeting before data base lock.

It is possible that a treatment has not been administered in the intended counterbalanced order of presentation. It is also expected that the sequence and period effects are minimal in this study if any. This study is not a full cross-over design, so period and sequence effects will not be assessed, without the consequence to bias the study conclusion.

Safety Population

The Safety Population will include all treated subjects. The Safety Population will be used for the safety data analysis.

9.6 Primary Endpoint Analyses

Primary and Secondary Speech Perception Endpoints:

SRT sentence scores in noise and words in quiet scores at different speech testing conditions will be listed and summarised descriptively by treatment group and study population. A Scatter plot or similar plot will be used to present the individual data by treatment group, and bar chart will be used to present the average paired difference and its standard error.

For the non-inferiority test of SRT sentence scores the 95% CI (alpha=0.025 one-sided) for the mean paired difference will be estimated. If the upper limit of the 95% CI of the mean paired difference is lower than 1dB, the treatment condition is regarded as non-inferior to the control in term of SRT sentence perception. The non-inferiority margin of 1dB for SRT is based on clinical consensus.

The same analysis method will be applied to the non-inferiority test for words in quiet scores (monosyllables). For the non-inferiority test of words in quiet scores, the 95% CI (alpha=0.025 one-sided) for the mean paired difference will be estimated. If the lower limit of the 95% CI of the mean paired difference is above -10%, the treatment condition is regarded as non-inferior to the control in

term of words in quiet perception. The non-inferiority margin of -10% for words in quiet scores (monosyllables) is also based on clinical consensus.

Only when the non-inferiority test for the above specified endpoint is successful, then a superiority test for the endpoint will be further conducted to assess the treatment effect.

9.7 Secondary Endpoint Analyses

See section 9.6

9.8 Exploratory Endpoint Analyses

See section 9.6

9.9 Safety Analyses

For AE/ADEs and DDs, the percentage of subjects who experienced at least one occurrence of each, will be summarised by intervention group. Any subjects who died, who discontinued an intervention due to an AE/ADEs, or who experienced a severe or an SAE/SADEs will be summarised separately.

9.10 Interim Analyses

The sound quality reports and general feedback form study participants will be analysed on an ongoing basis and these will be used to improve the product. No formal interim analysis is planned for the speech perception assessments.

10 INFORMED CONSENT PROCESS

The Investigator shall obtain written informed consent from the subject using an approved ICF prior to any clinical investigation-related examination or activity. The rationale of the clinical investigation, as well as the risks and benefits, what participation will involve, and alternatives to participation will be explained to the subject. Ample time will be provided for the subject to enquire about details of the clinical investigation and to decide whether to participate.

All questions about the clinical investigation shall be answered to the satisfaction of the subject or the subject's legally acceptable representative. Subjects shall not be coerced or unduly influenced to participate or to continue to participate in a clinical investigation.

Each subject (or their legally authorised representative) and the person who conducted the informed consent discussion, shall sign and date the Informed Consent Form (ICF). Where required, a witness shall sign and personally date the ICF. A copy of the signed ICF shall be given to the subject. The original signed ICF shall be archived in the Investigator's Site File or subject file at the investigational site.

The subject, or the subject's legally authorised representative, shall be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the clinical investigation. The communication of this information must be documented as an update to the ICF and re-consent of the subject.

For Belgium only: The principal investigator of the clinic (GZA Sint-Augustinus Antwerp) or study staff of the principal investigator shall be responsible for subject recruitment and obtaining Informed

Consent of the clinical investigation. The sponsor principal investigator of CTC will receive a copy of the signed Informed Consent Form.

11 ADVERSE EVENTS AND DEVICE DEFICIENCIES

11.1 Definitions

11.1.1 Adverse Event

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons whether or not related to the medical device or the procedures required for implant or use.

NOTE 1: This definition includes events related to the medical device or the comparator device.

NOTE 2: This definition includes events related to the procedures involved.

NOTE 3: For users and other persons, this definition is restricted to events related to medical devices.

11.1.2 Adverse Device Effect

An adverse device effect (ADE) is an AE related to the use of a medical device.

NOTE 1: This includes any AE resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the medical device.

NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the medical device.

11.1.3 Serious Adverse Event

A serious adverse event (SAE) is any AE that:

1) led to a death,

2) led to a serious deterioration in the health of the subject that either resulted in:

- a life-threatening illness or injury, or
- a permanent impairment of, or damage to, a body structure or a body function, or
- in-patient hospitalisation or prolonged hospitalisation, or
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment or damage to a body structure or a body function, or
- Chronic disease.

3) led to foetal distress, foetal death or a congenital physical or mental abnormality, or birth defect

NOTE: Planned hospitalisation for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a SAE.

11.1.4 Serious Adverse Device Effect

A serious adverse device effect (SADE) is an ADE that has resulted in any of the consequences characteristic of a SAE.

11.1.5 Unanticipated Serious Adverse Device Effect

An unanticipated serious adverse device effect (USADE) is a SADE, which by its nature, incidence, severity, or outcome has not been identified in the current version of the Nucleus 8 SP Hazards Analysis.

NOTE: An anticipated serious adverse device effect is an effect, which by its nature, incidence, severity, or outcome has been identified in the Nucleus 8 SP Hazards Analysis.

11.1.6 Adverse Events of Special Interest

Not applicable

11.1.7 Device Deficiency

A Device Deficiency (DD) is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance.

NOTE: Device Deficiencies include malfunctions, use errors, and inadequate labelling or information supplied by the manufacturer.

11.2 Recording and Handling of Adverse Events

Subjects shall be carefully monitored during the clinical investigation and the investigator should enquire about AEs at investigation visits.

All AEs. will be recorded from the time of first use of the IMD. AE recording will continue for each subject until completion of their End of Study visit. Ongoing SAEs and SADEs will be followed for 30 days, or until resolution or stabilisation of the event, whichever comes first.

Source notes should indicate the evaluation for AEs, even if there was none to report. All required AEs will be reported if observed, even if anticipated and/or acknowledged as a risk factor in the consent.

All AEs will have the following information documented: start and stop dates, action taken, outcome, severity and investigators opinion on the potential relationship to the IMD and study procedures. If an AE changes in severity, the most severe (highest) grade will be captured for that event on the Adverse Events CRF.

11.2.1 Assessment of Severity

The Principal Investigator (or qualified delegate) will make an assessment of severity for each event based on clinical judgement. The intensity of each event recorded in the CRF should be assigned to one of the following categories:

Mild	An event that is easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
Moderate	An event that is sufficiently discomforting to interfere with normal activities
Severe	An event which is incapacitating and prevents normal everyday activities

11.2.2 Assessment of Causality

The Investigator will assess the potential causal relationship of each event, using clinical judgement. Alternative causes, such as natural history of underlying diseases, other risk factors and the temporal relationship of the event to the IMD and/or comparator product will be considered and investigated. The causal relationship to the IMD and/or comparator is to be assessed by the Investigator (or medically qualified delegate) and should be assessed using the following classifications:

Not related	Relationship to the medical device or procedures can be excluded when: • the event is not a known side effect of the product category the device belongs to or of similar devices and procedures; • the event has no temporal relationship with the use of the device or the procedures; • the event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; • the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the event; • the event involves a body-site or an organ not expected to be affected by the device or procedure; • the event can be attributed to another cause (for example, an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors); • the event does not depend on a false result given by the investigational medical device used for diagnosis, when applicable; • harms to the subject are not clearly due to use error; In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event.
Unlikely related	The relationship with the use of the medical device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
Possibly related	The relationship with the use of the medical device is weak but cannot be ruled out completely. Alternative causes are also possible (for example, an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possibly related.
Probably related	The relationship with the use of the medical device seems relevant and/or the event cannot be reasonably explained by another cause, but additional information may be obtained.

Definitely related	The event is associated with the medical device or with procedures beyond reasonable doubt when: • the event is a known side effect of the product category the device belongs to or of similar devices and procedures; • the event has a temporal relationship with the medical device use/application or procedures; • the event involves a body-site or organ that – the medical device or procedures are applied to – the medical device or procedures have an effect on; • the event follows a known response pattern to the medical device (if the response pattern is previously known); • the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the event (when clinically feasible); • other possible causes (for example, an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; • harm to the subject is due to error in use; • the event depends on a false result given by the medical device used for diagnosis, when applicable; In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event.

11.2.3 Assessment of Seriousness

The Investigator will assess the seriousness of each event according to clinical judgement and the definition provided in section 11.1.3.

11.2.4 Assessment of Expectedness

An event should be considered unanticipated if the nature, severity, or frequency of that event is not consistent with the applicable safety reference information, such as the risk analysis report, hazards analysis, IB, or Product Information/IFU if the product is approved for marketing.

For this clinical investigation the listed items in Section 8.2 and 8.3 of this CIP are anticipated ADEs.

Anticipated	An adverse device effect (ADE) which by its nature, incidence, severity, or outcome is consistent with the applicable safety reference information (for example, IB, IFU).
Unanticipated	An adverse device effect (ADE) which by its nature, incidence, severity, or outcome is not consistent with, or has not been identified in the applicable safety reference information (for example, IB, IFU).

11.3 Recording and Handling of Device Deficiencies

Subjects shall be carefully monitored during the clinical investigation and routinely questioned about DDs at investigation visits. Source notes should indicate the evaluation for DDs, even if there are none to report.

The Investigator shall assess if the DD led to an AE or could have led to a serious medical occurrence (serious adverse device effect) if;

a) suitable action had not been taken,

b) intervention had not been made, or,

c) circumstances had been less fortunate

All DDs will be documented in the source notes and the DD page of the CRF.

11.4 Reporting Responsibilities

The Investigator is responsible for reporting all AEs and DDs in the CRF.

11.4.1 Investigator Reporting of Serious Adverse Events

All AEs meeting the criteria for an SAE, or DD that could have led to an SADE, must be reported to the Sponsor by five working days.

Reporting is achieved through completion of the events details in the Adverse Event page of the eCRF

The Investigator shall always provide an assessment of causality at the time of the initial report, as described in section 11.2.2 ‘Assessment of Causality’. If data obtained after reporting indicates that the assessment of causality is incorrect, then the SAE form may be appropriately amended, signed, dated, and resubmitted to the Sponsor.

If the Investigator does not have all other information regarding an SAE, he/she will not wait to receive additional information before reporting the event. The reporting forms shall be updated when additional information is received.

The Investigator is responsible for reporting of safety events to their local EC using the applicable report form, in accordance with local regulations.

11.4.2 Sponsor Notification of Events

The Sponsor is responsible for reviewing all safety data to evaluate potential causality and anticipation of all ADEs.

The Sponsor is also responsible for reporting all reportable events according to the requirements and timelines of the regulatory authorities relevant to this clinical investigation, and shall conduct an expedited assessment of all SAEs, unanticipated ADEs, DDs that could have led to an SADE.

For Belgium only: The sponsor is responsible for reporting serious adverse events (SAE) to Famhp (Federal Agency for Medicines and Health Products): ct.rd@famhp.be, by using the European form. Reporting must be a) immediately for any SAE or device deficiency (DD) that might have led to a SAE resulting in death or threat to life, or is associated with imminent risk of death, or for any serious injury or disease warranting rapid curative therapy or any new information relating thereto, and b) immediately and in any case no later than 7 days for other SAE/SADEs. In case an initial notification of an SAE/SADE would be incomplete, on receipt of additional information the Sponsor must submit a clearly referenced and numbered follow-up report of the event.

The Safety Monitor for AE/DD assessment and any AE/DD related queries is:

Name of contact person of the Sponsor:	[redacted]
Country and time zone:	Australia, Australian Eastern Standard Time
Phone number:	[redacted]
Email:	[redacted]

11.5 Independent Data Monitoring Committee

The risks associated with the use of the investigational device and the subject's participation in the clinical investigation is described in Section 8.3 of this document. The subjects in the proposed clinical investigation will be able to revert to their own processor if there are sound quality issues or dissatisfaction with the investigational sound processors. As this study is an open label study, no Independent Data Monitoring Committee (IDMC) has been established for this clinical investigation.

12 Device Accountability

Supply of investigational medical devices will be recorded using the Sponsor Device Tracking Form and Software Tracking Form by the sponsor representative. Investigational medical device(s) will be quarantined at the investigational site and clearly labelled to identify exclusively for use in a clinical investigation.

Subject level device supply will be tracked using the Sponsor's Individual Subject Accountability Log Form by the principal investigator.

All device(s) that have been identified with Device Deficiencies will be returned to Device Analysis for analysis and archiving.

Contact information regarding the IMD is provided below.

Name of contact person of the Sponsor:	[redacted]
Country and time zone:	Australia, Australian Eastern Standard Time
Phone number:	+[redacted]
Email:	[redacted]

13 Deviations from the Clinical Investigation Plan

The Investigator(s) must not deviate from the CIP, except in case of an emergency to protect the safety and well-being of the subject(s). Such deviations will be documented by the site personnel in the source documentation for the subject and reported to the relevant EC as per institutional requirements and to the Sponsor as soon as possible, but not later than five working days from the date of the emergency.

If there is a deviation from CIP-defined assessments or parts thereof are omitted or completed incorrectly, the deviation will also be documented by the site personnel in the source documentation for the subject. Depending on the type or severity of the deviation the Investigator may be required to

notify the EC, particularly if the deviation potentially impacts subject safety, performance of IMD, or data integrity.

All CIP deviations will be documented in the eCRF to enable analysis and reporting by the Sponsor in the Clinical Investigation Report (CIR), or to the relevant regulatory authority(s), if applicable.

Gross misconduct on behalf of an Investigator, such as intentional non-compliance with CIP or GCP requirements or fraud, will result in disqualification of the Principal Investigator and/or Investigational Site from participation in the investigation. Data provided by the Principal Investigator or Investigational Site will be excluded from the per-protocol analysis group.

14 DATA MANAGEMENT

The CRF will capture the datapoints necessary to determine the subject status according to the criteria described in section 7.2.5.

Source data will be captured in clinic notes, paper-based source data worksheets, or printed directly from testing software. If electronic medical records do not permit read only access for monitoring purposes, a certified printout must be provided.

Data collection will be performed using [redacted] electronic data capture (EDC) on electronic Case Report Forms (eCRFs). Site staff will be trained on the completion of the eCRFs prior to obtaining access to the system, and will have their own Login/Password. Access to clinical study information will be based on an individual's role and responsibilities.

[redacted] uses role-based user permissions for data entry, viewing, and reporting options. All communications between users and the EDC server are encrypted. Web servers are protected by a managed firewall. This application is designed to be in compliance with applicable regulations including 21 CFR Part 11.

The application will include programmed data consistency checks and supports manual generation of data clarifications/queries, including documentation of site responses. The application maintains a comprehensive audit trail for all data entered, including updates and queries, and documents the time that each entry occurred and who made the entry.

Principal Investigators will affirm that the data for each subject at their site is accurate and complete by way of an electronic signature.

15 CONFIDENTIALITY

The investigator and site staff will collect and process personal data of the subjects in accordance with governing data privacy regulations.

Data will be reported to the Sponsor on CRFs or related documents (for example, questionnaires). Subjects will be identified on CRFs and other related documents only by a unique subject identification code and shall not include the subject's name or other personal identifiable information. Completed CRFs or related documents are confidential and will only be available to the Investigator and site staff, the Sponsor and their representatives, and if requested to the Ethics Committee and national regulatory authorities. Publications or submission to a regulatory authority shall not disclose the identity of any subject.

16 ETHICS COMMITTEE AND REGULATORY AUTHORITY APPROVAL

The clinical investigation will not commence prior to the written favourable opinion or approval from the EC and or regulatory authority (if appropriate) is obtained.

The final Sponsor-approved version of the CIP, Informed Consent Form, and other necessary documents shall be submitted to the EC. A copy of the EC opinion/approval shall be provided to the Sponsor.

The Investigator shall forward to the Sponsor, for review and approval, any amendment made to the approved ICF and any other written information to be provided to the subject prior to submission to the EC.

The Sponsor and Principal Investigator will continue communications with the EC, as required by national regulations, the clinical investigational plan, or the responsible regulatory authority.

Any additional requirements imposed by the EC or regulatory authority will be implemented by the Sponsor.

The Investigator shall submit the appropriate documentation if any extension or renewal of the EC approval is required. In particular, substantial amendments to the CIP, the ICF, or other written information provided to subjects will be approved in writing by the EC.

The Investigator shall report to the EC any new information that may affect the safety of the subjects or the conduct of the clinical investigation. The Investigator will send written status summaries of the investigation to the EC regularly, as per local EC requirements.

Upon completion of the clinical investigation, the Investigator shall provide the EC with a brief report of the outcome of the clinical investigation, as per local EC requirements.

The clinical investigation is covered by clinical trial insurance, meeting the requirements of the participating countries.

17 SUSPENSION OR PREMATURE TERMINATION

The Sponsor will discontinue the clinical investigation site if:

1) major non-adherence to the CIP or GCP principles is occurring
2) it is anticipated that the subject recruitment will not be adequate to meet the objectives of the clinical investigation

An ongoing clinical investigation may be discontinued in case of:

1) device failure
2) serious or intolerable ADE, leading to the explant or discontinued use of the device
3) subject's death

For Belgium only: Upon end of the clinical investigation, the sponsor shall notify the regulatory authority within 15 days. In the case the clinical investigation is temporarily halted or terminated early, notification of this shall be made to the regulatory authority within 15 days. Justification for the halt or

termination shall be included. If either situation is on safety grounds, then the reporting timeframe is 24 hours.

18 AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

No changes in the CIP or investigation procedures shall be made without mutual agreement of the Principal Investigator and the Sponsor. This agreement will be documented as a CIP amendment. Amendments will require notification to the Ethics Committees (ECs) by the Principal Investigators (and to the relevant regulatory authority(s) by the Sponsor, if applicable).

19 RECORD KEEPING AND RETENTION

Data generated from the clinical investigation will be stored in a limited-access file area and be accessible only to representatives of the study site, the Sponsor and its representatives, and relevant health authorities/regulatory agencies. All reports and communications relating to study subjects will identify subjects only by subject unique identification code. Complete subject identification will be maintained by the Investigator. This information will be treated with strict adherence to professional standards of confidentiality.

The investigator must retain study-related records for a period of at least 15 years after completion of the investigation or after the last device was placed on the market, if the IMD has market authorisation.

The Sponsor will notify the Principal Investigator when records are no longer needed. The Investigator will not discard any records without notifying the Sponsor. If the Principal Investigator moves from the current investigational site, the Sponsor should be notified of the name of the person who will assume responsibility for maintenance of the records at the investigational site or the new address at which the records will be stored. The Investigator will notify the Sponsor as soon as possible in the event of accidental loss or destruction of any study documentation.

20 PUBLICATION POLICY

This clinical investigation will be prospectively registered at a public clinical trial registry.

Investigators will be able to publish and/or present the data generated from the clinical investigation after mutual agreement between the Coordinating Investigator, the Principal Investigators, and the Sponsor prior to investigation start. Manuscript authorship and responsibilities will be in accordance with guidelines and recommendations provided by the International Committee of Medical Journal Editors (ICMJE) to enable communication in a timely manner. All contributors who do not meet the criteria for authorship will be listed in an acknowledgments section of the publication.

21 STATEMENTS OF COMPLIANCE

This clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki[7], International Standard ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice[8], and any regional or national regulations, as applicable.

22 QUALITY CONTROL AND ASSURANCE

In accordance with Cochlear's Quality Management System, all clinical investigations shall be conducted according to internationally recognised ethical principles for the purposes of obtaining clinical safety and performance data about medical devices.

The Sponsor employees (or designee) shall use standard operating procedures (SOP) to ensure that clinical study procedures and documentation are consistently conducted and compliant with the ISO 14155 Standard, Good Clinical Practice (GCP), and applicable local regulations.

22.1 Monitoring

The Sponsor will perform on-site and remote monitoring visits as frequently as necessary to oversee conduct, data collection and record keeping by sites. The clinical investigation monitoring plan is a separate document describing all the activities performed during monitoring, and close out.

Monitoring activities may be performed by Avania CRO/TRIUM Clinical Consulting according to a pre-approved Statement of Work.

22.2 Audits

An Investigator must, in reasonable time, upon request from a relevant health authority or regulatory agency, permit access to requested records and reports, and copy and verify any records or reports made by the Investigator. Upon notification of a visit by a regulatory authority, the Investigator will contact the Sponsor immediately.

The Investigator will grant the Sponsor representatives the same access privileges offered to relevant health authority or regulatory agents, officers, and employees.

23 TRADEMARKS AND COPYRIGHT

24 REFERENCES

Internal

Clinical Investigation Report: Acceptance and Performance with the Nucleus 7 Cochlear Implant System with Adult Recipients (D1376556)

Clinical Investigation Report: Clinical Evaluation of Spatial NR (BTE) Investigation (556125)

Clinical Investigation Report: Clinical Evaluation of the Spatial NR Noise Reduction Algorithm (D1309506)

Clinical Investigation Report: Phase 2, Clinical Evaluation of Spatial Noise Reduction Integrated with SCAN in the CP900 Sound Processor (D1119540)

External

1. Warren CD, Nel E, Boyd PJ. Controlled comparative clinical trial of hearing benefit outcomes for users of the Cochlear™ Nucleus ® 7 Sound Processor with mobile connectivity. *Cochlear Implants Int*. 2019;20(3). doi:10.1080/14670100.2019.1572984

2. Sivonen V, Willberg T, Aarnisalo AA, Dietz A. The efficacy of microphone directionality in improving speech recognition in noise for three commercial cochlear-implant systems. *Cochlear Implants Int*. 2020;21(3). doi:10.1080/14670100.2019.1701236

3. Peterson GE, Lehiste I. Revised CNC lists for auditory tests. *J Speech Hear Disord*. 1962;27(February):62-70. doi:10.1044/jshd.2701.62

4. Wouters J, Damman W, Bosman A. Vlaamse opname van woordenlijsten voor spraakaudiometrie. *Vlaam Ver voor Logop*. 1994;7(6):28-34.

5. Dawson PW, Hersbach AA, Swanson BA. An adaptive Australian Sentence Test in Noise (AuSTIN). *Ear Hear*. 2013;34(5):592-600. doi:10.1097/AUD.0b013e31828576fb

6. Van Wieringen A, Wouters J. LIST and LINT: Sentences and numbers for quantifying speech understanding in severely impaired listeners for Flanders and the Netherlands. *Int J Audiol*. 2008;47(6). doi:10.1080/14992020801895144

7. World Medical Association Declaration of Helsinki. *World Medical Association. World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects*. Vol 15.; 2004. doi:10.3917/jib.151.0124

8. ISO. Clinical investigation of medical devices for human subjects — Good clinical practice. 2011;14155:14155.

25 CHANGE HISTORY

Version	Change	Rationale
1.0	Change has been made to the standard exclusion criteria: Currently participating, or participated within the last 30 days, in another interventional clinical investigation/trial involving an investigational drug or device. To Currently participating, or participated in another interventional clinical study/trial in the past 30 days, or (if less than 30 days) the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation.	Cochlear sponsored trials looking at sound processors and signal processing are not treating life-threatening illnesses, they are low risk and low intensity for the patient. The potential confounding effect of a Cochlear investigational device is understood and there is no expected washout period expected. There is no need for patients to enrol without a 30-day break if the previous trial was a Cochlear sponsored trial.
2.0	Addition of Melbourne study site. Change wording in sound quality procedural sections from 'may' to 'will'	Due to covid-related restrictions, recruitment at the Sydney site has not started. The addition of the Melbourne site is aimed to improve recruitment rates. Change in wording has been made to ensure that sound quality is assessed with every subject.

Version	Change	Rationale
3.0	Minor change of title to be consistent with public registry Increase in number of planned investigational sites from 2 to 4 to include Belgium sites – the recruiting centre (GZA Sint-Augustinus Antwerp) and the testing site (CTC) Increase in recruitment period from 1 month to 2 Modification of inclusion criteria number 8, to include languages used in speech testing rather than just English Addition of optional screening visit to allow country and site-specific screening procedures Addition of Flemish speech tests to objectives, procedures, endpoints and hypotheses Addition of Belgian specific requirements to the Informed Consent process, Sponsor notification of events, and Suspension or Premature termination Addition of Belgian Clinical Research Organisation Addition of description of CDI tool fitting software, and fitting procedures	Due to covid-related restrictions, recruitment at the Sydney and Melbourne sites have not started. The addition of the Belgium sites (both recruiting site and testing site) is aimed to improve recruitment rates. To facilitate the inclusion of these sites changes and additions were made according to local Belgian requirements, and to facilitate the inclusion of the equivalent local speech perception tests and recruitment requirements. In addition, a local Belgian CRO was added to support approval and execution of the study. The CDI tool description and procedures have been added to provide additional information to the investigator to support programming of the investigational programs.

APPENDICES

APPENDIX 1: STATEMENT/DECLARATION OF DEVICE CONFORMITY

STATEMENT OF CONFORMITY FOR UNAPPROVED DEVICE

Clinical Investigation Details:

Clinical Investigation ID:	CLTD5804
Sponsor of Investigation:	Cochlear Limited, 1 University Avenue, Macquarie University, NSW 2109, Australia

Device and Manufacturer Details:

Device Manufacturer:	Cochlear Limited, 1 University Avenue, Macquarie University, NSW 2109, Australia
Investigational Device:	Nucleus 8 Sound Processor including: CP1110 Processing Unit CP1110 Rechargeable Battery Modules CP1110 Slimline Coil with CP1000 retention magnets Custom Sound (Version 7.0) CDI Tool (Version 4.20.10.1)

We, Cochlear Limited, declare that, where appropriate, technical and biological and pre-clinical evaluations have been conducted and, as a result, the investigational devices conform to the applicable general safety and performance requirements (as specified in Annex I of Regulation (EU) 2017/745), apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects, the users and third persons.

The Device incorporates no materials of animal or human origin.

All supporting documentation is retained under the premises of the manufacturer.

Name:	[redacted]
Position:	Senior Manager, Regulatory Affairs – External Devices
Signature:	
Date:	

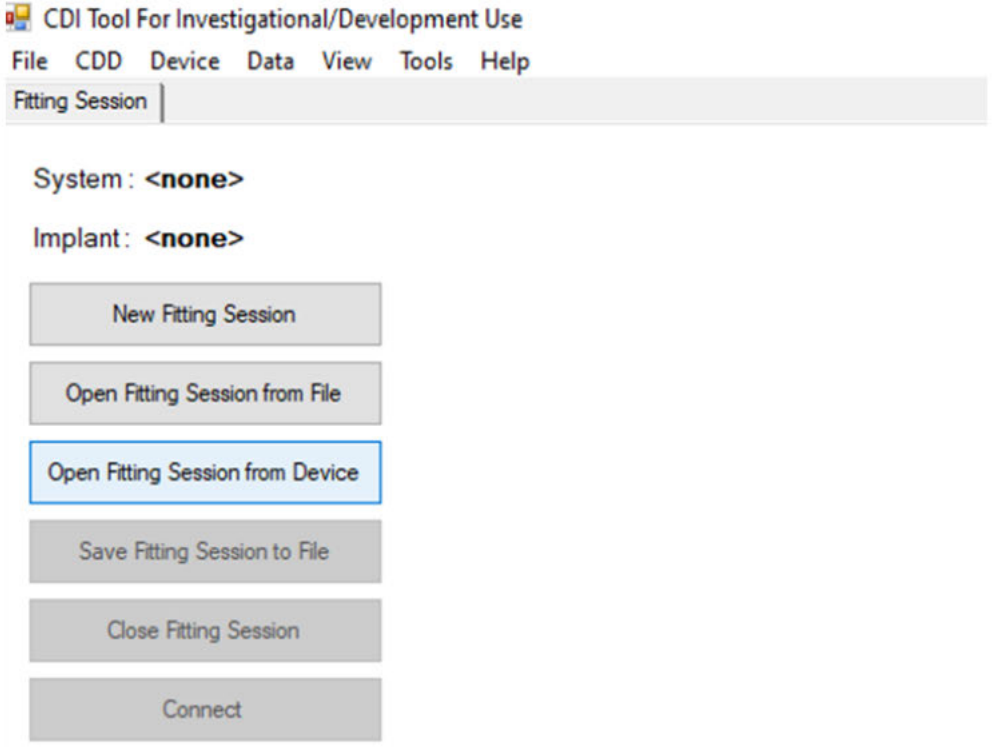
APPENDIX 2: CONFIGURING TEST CONDITIONS FOR N8 CLINICAL STUDY - SETUP

A. Configuring Test Conditions for N8 Clinical Study – Setup

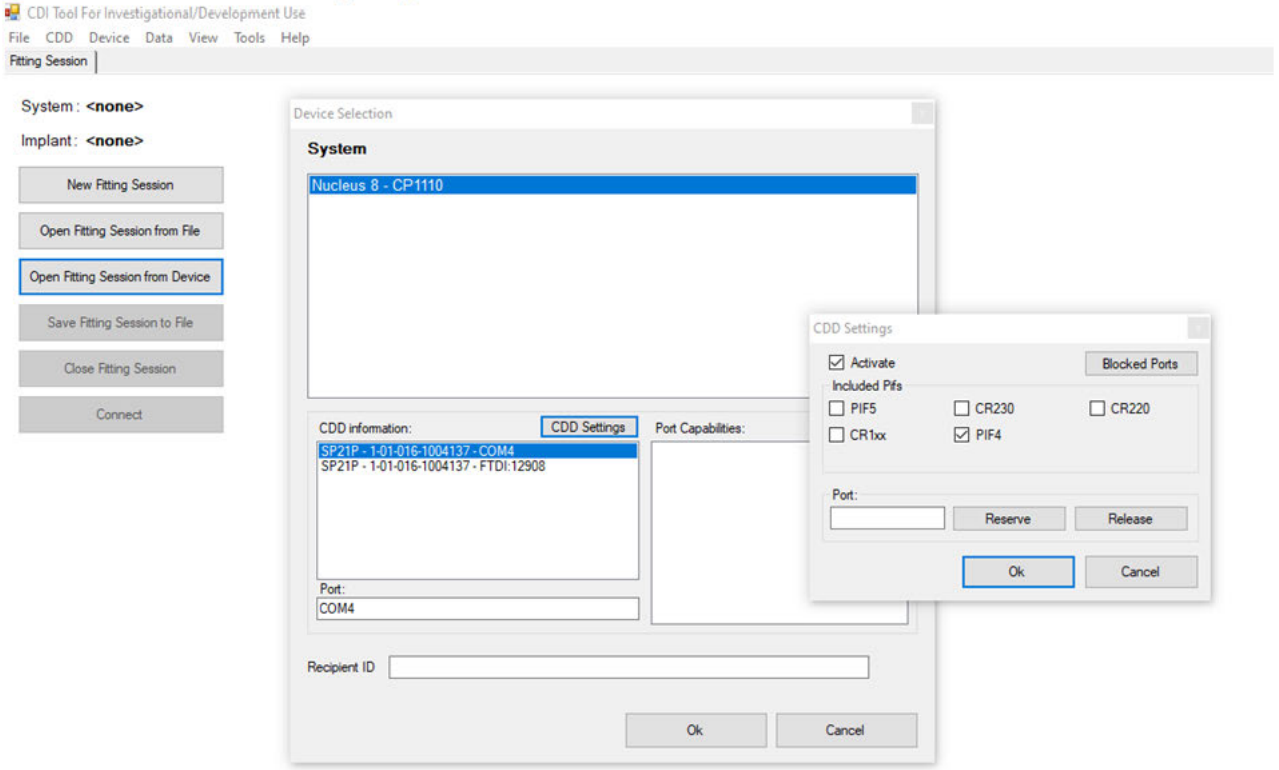
1. Ensure that the device has been **reset** if the device has already been used for other clinical trial tests. If the device needs to be reset, please refer to section D
2. **Fitting SW:** convert SP17 map to a SP21 map using the Fitting SW
3. **Fitting SW:** load the converted map onto a SP21 device
4. **CDI Tool:** open a fitting session for connected device
    a. Open the CDI Tool by double-clicking on the "CDITool.exe"

Name	Date modified	Type	Size
Cochlear.Cdi.CdiTool.Plugin.SystemX.dll	11/02/2021 9:30 PM	Application extension	255 KB
Cochlear.Cdi.CICx.SP21.dll	11/02/2021 9:25 PM	Application extension	36,708 KB
Cochlear.Nrt.dll	11/02/2021 9:09 PM	Application extension	1,742 KB
libblas32.dll	11/02/2021 8:59 PM	Application extension	1,342 KB
liblapack32.dll	11/02/2021 8:59 PM	Application extension	4,264 KB
cditool.ini	11/02/2021 8:59 PM	Configuration settings	5 KB
SP21_MemoryMap.xml	11/02/2021 3:40 PM	XML Document	3,345 KB
CDITool.exe	10/02/2021 5:06 PM	Application	1,464 KB
Cochlear.Cdi.CdiTool.Plugin.dll	10/02/2021 4:58 PM	Application extension	11 KB
Cochlear.Cdi.dll	10/02/2021 4:52 PM	Application extension	155 KB
Cochlear.Cdi.IDiagnosticsCIC34.dll	10/02/2021 4:06 PM	Application extension	69 KB
Cochlear.Cdd.dll	10/02/2021 11:45 AM	Application extension	859 KB
Python.Runtime.dll	27/01/2021 4:46 PM	Application extension	101 KB
TedCommunication.dll	27/01/2021 4:46 PM	Application extension	55 KB
clr.pyd	27/01/2021 4:46 PM	Python Extension Module	4 KB
Data	3/02/2021 10:21 AM	File folder	
Output	3/02/2021 10:21 AM	File folder	

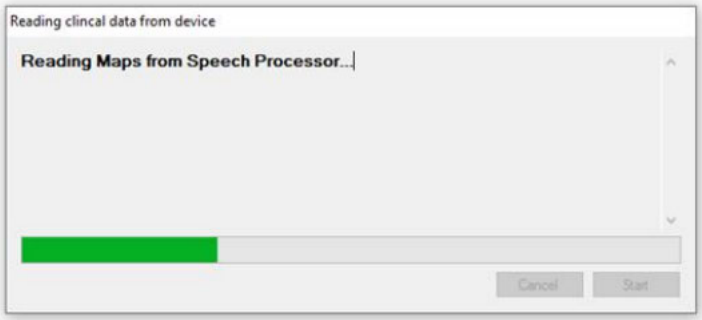
b. Ensure a SP21 device is connected.
c. Click on "**Open Fitting Session from Device**" to read data from the connected device.



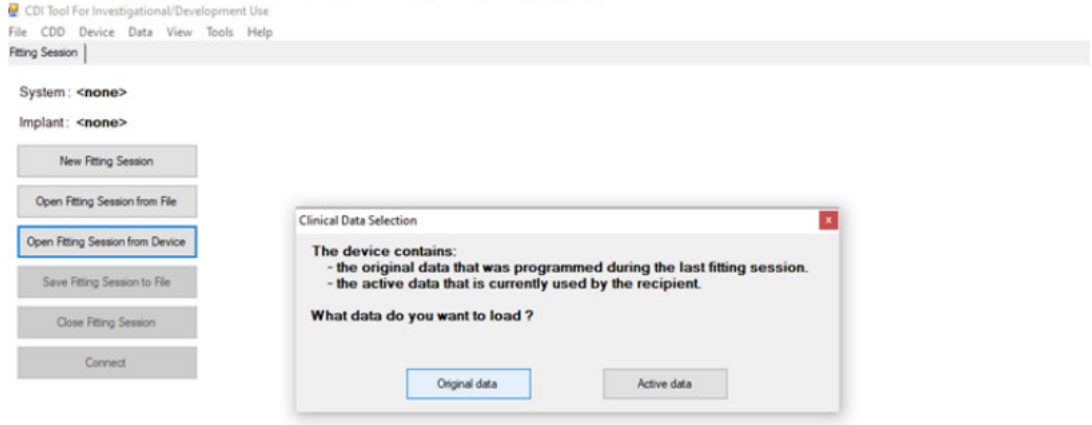
d. Select the following settings and press "**Ok**".
   i. Note: "**CDD Settings**" only needs to be set if the "**CDD information**" is blank.



ii. Once you clock "**Ok**" the following window should pop up.



e. Click on "**Original data**" when the following window pops up.

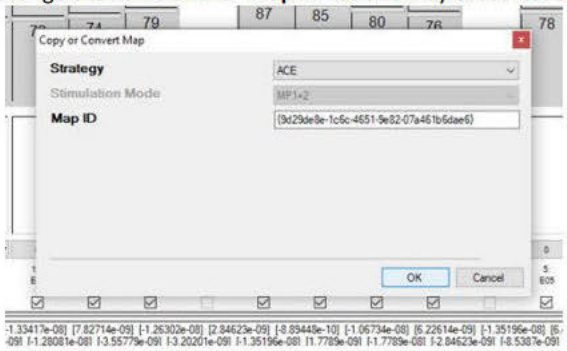


5. **CDI Tool:** duplicate maps and configure parameters (continues in section 0)
   a. Click on "**Maps**" tab.

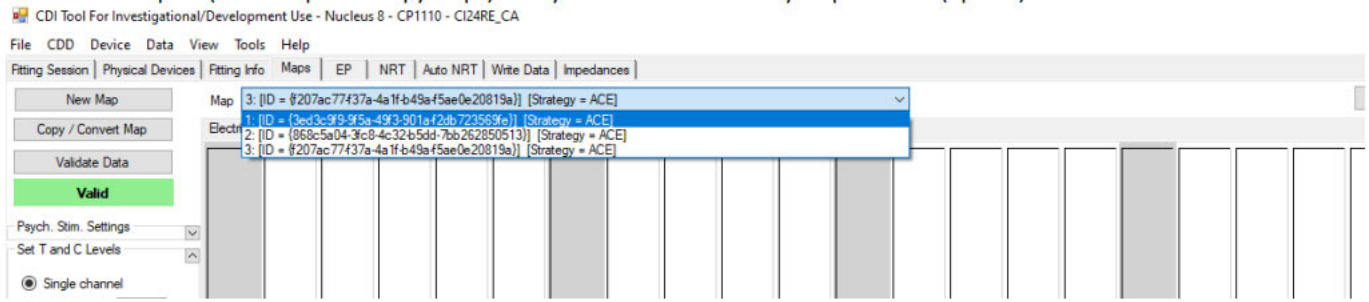
   b. Click on "**New Map**" to create a new map.
   c. Click "**Copy / Convert Map**" to duplicate the map.

[redacted]

i. Click "**Ok**" when the following window pops up.
   a. Note: do not change the name of the "**Map ID**" as this may cause issues.



d. Repeat (“new map” OR “copy map”) until you have however many maps needed (up to 4).



B. CP1110 Configurations for "Speech in Quiet" and "Speech in Noise" Sessions

"Speech in Quiet" Configuration 1: SNR-NR On

"Speech in <u>Quiet</u>" Configuration 2: SNR-NR Off (Expander On)

a. Check that "**Noise Suppression Enabled**" (in Electric Stimulator parameter section) is **unticked** to **disabled** SNR-NR.
b. Check that "**Noise Floor Expansion Enabled**" (in Front End parameter section) is **ticked** to enable Noise Floor Expansion.

i. Note: SNR-NR and Noise Floor Expansion are **mutually exclusive** – if both are enabled the map is invalid and both settings will be highlighted in red.

"Speech in Quiet" Configuration 3: Standard, Forward Focus On (Moderate)

a. Check that "**Spatial Noise Reduction Enabled**" (in Front End parameter section) is **ticked** to enable Forward Focus.
b. Check that the "**Directionality**" (in Front End parameter section) is set to "**Standard**".
c. Check that the "**Spatial Nr Strength**" (in Front End parameter section) is set to "**9**" (moderate).

"Speech in Noise" Configuration: BEAM, Forward Focus On (Strong)

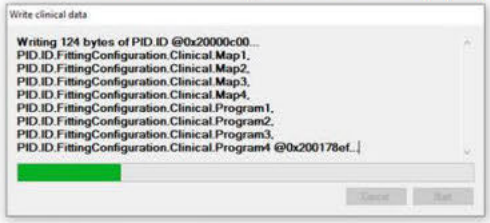
a. Check that "**Spatial Noise Reduction Enabled**" (in *Front End parameter* section) is **ticked** to enable Forward Focus.
   Note: *Ignore* the setting of the same name that is in the *System Data* section!
b. Check that the "**Directionality**" (in Front End parameter section) is set to "**Beam**".
c. Check that the "**Spatial Nr Strength**" (in Front End parameter section) is set to "**14**" (strong).

C. Writing Configured Maps to Device

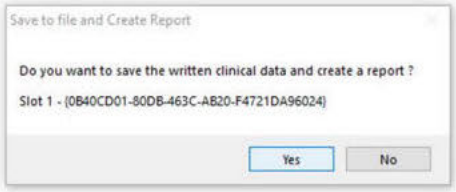
1. **CDI Tool:** write maps to device
    a. Click on "**Write Data**" tab.

    b. Assign a map to each program (as needed), then click on "**Write Clinical Data**".

i. Once you click "**Write Clinical Data**" the following window should pop up.



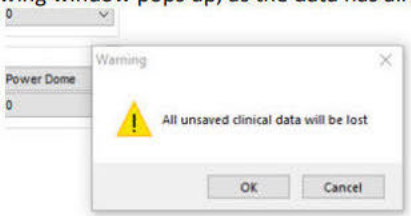
c. Click on "**Yes**" to save the written clinical data to a file.
   i. Note: save to a known location of choice, so that it is accessible in the future.



2. **CDI Tool:** close the fitting session
   a. Click on "**Fitting Session**" tab.

   b. Click on "**Close Fitting Session**".

i. Click "**Ok**" when the following window pops up, as the data has already been saved.



d. Close the CDI Tool window.

3. Connect a battery to the device to put it in standalone mode. The device is now ready to test!

Summary of Parameters

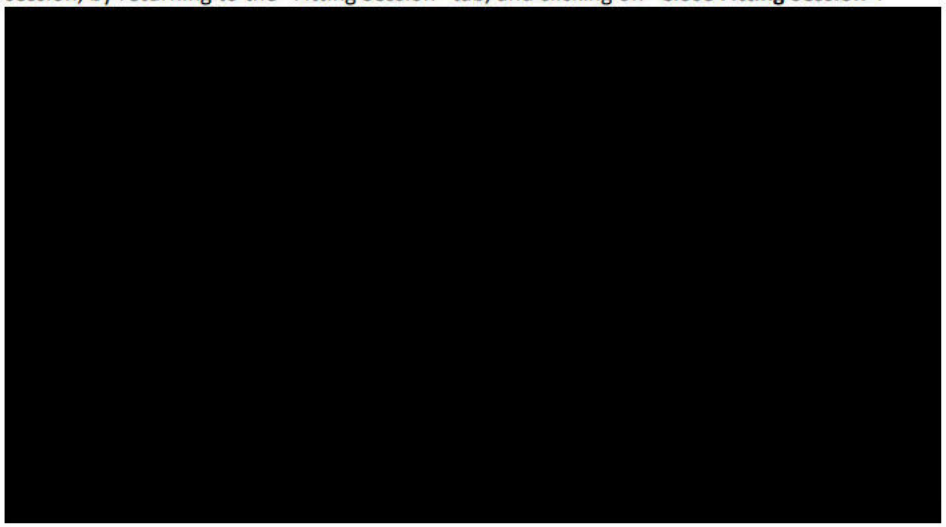
N8 Study	Speech in Quiet			Speech in Noise
Configuration	SNR-NR On	SNR-NR Off (Expander On)	Standard, FF On (Moderate)	BEAM, FF On (Strong)
Noise Suppression Enabled (Electric Stimulator Parameter)	Ticked	Un-ticked	Un-ticked (default value)	Un-ticked (default value)
[redacted]				
Spatial Noise Reduction Enabled (Front End Parameter)	Un-ticked (default value)	Un-ticked (default value)	Ticked	Ticked
Directionality (Front End Parameter)	N/A	N/A	Standard	Beam
Spatial Nr Strength (Front End Parameter)	N/A	N/A	9 (Moderate)	14 (Strong)

D. Resetting a Device

1. Click on "**Physical Devices**" tab.

2. Click on "**Write Firmware**" in the **second column** (Cochlear.Cdi.CICx_SP21.Implementation.**SpeechProcessor**).

3. Close the fitting session, by returning to the "Fitting Session" tab, and clicking on "**Close Fitting Session**".



Signature Page for VV-TMF-04139 v3.0

Reason for signing: Approved	Name: [redacted] Role: A Date of signature: 16-Sep-2021 10:07:04 GMT+0000

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