Clinical Investigation Plan

Investigation Title: A pre-market, open-label, within subject study, of acceptance and performance of the CP1170 sound processor in experienced adult cochlear implant recipients compared with the CP1150 sound processor and their current sound processor.

Short Title:	**POLAR**
CIP Number:	**CLTD5836**
Version and Date:	**Refer to system version control**
Sponsor:	***Cochlear Limited*** ***1 University Avenue*** ***Macquarie University NSW 2109*** **Australia**

This clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, International Standard ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good Clinical Practice, and any regional or national regulations, as applicable.

NCT number: NCT05619575
Approval date: 04-Apr-2023

Manufacturer	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia
Sponsor Organisation(s)	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia
Funding Source	Sponsoring Organisation
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Safety Contact	Cochlear Limited *CLTD-SafetyMonitor@cochlear.com*

INVESTIGATOR AGREEMENT

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.

I also agree that my personal information may be provided to regulatory agencies and public clinical trial registry platforms, and stored in their systems in order to comply with regulatory requirements. Examples of the type of personal information include my name, signature and summary of qualifications.

Name	**Title**
[redacted]	Principal Research Audiologist
Site Name	**Site Address**
Cochlear Headquarters	1 University Avenue Macquarie University NSW 2109
Signature	**Date**

TABLE OF CONTENTS

1 DEFINITIONS AND ABBREVIATIONS

Term	Description
ADE	Adverse Device Effect
AE	Adverse Event
BTE	Behind-the-Ear
CER	Clinical Evaluation Report
CI	Cochlear Implant
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
CRO	Contract Research Organisation
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
EDC	Electronic Data Capture
EOS	End of Study
GCP	Good Clinical Practices
IB	Investigator's Brochure
ICF	Informed Consent Form
IDMC	Independent Data Monitoring Committee
IMD	Investigational Medical Device
NCA	National Competent Authority
OTE	Off-the-Ear
PI	Principal Investigator
PIL	Principal Investigator List
PMS	Post-Market Surveillance
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SNR	Signal to Noise Ratio

Term	Description
SSQ12	Short form of the Speech, Spatial and Qualities of Hearing scale
S-N-	Describes the signal and noise configuration. E.g. S0N0 is signal and noise both presented at 0 degrees azimuth; S0NCI is signal presented at 0 degrees azimuth and noise presented on CI side (test ear)
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

2 CLINICAL INVESTIGATION SYNOPSIS

Investigation title	A pre-market, open-label, within subject study, of acceptance and performance of the CP1170 sound processor in experienced adult cochlear implant recipients compared with the CP1150 sound processor and their current sound processor.
Short title	POLAR
Investigation number	CLTD5836
Name of investigational medical device(s)	**CP1170 Sound Processor:** unapproved off-the-ear (OTE) sound processor manufactured by Cochlear Limited, to be commercially known as Kanso 3. **Custom Sound Pro (Version 7.0.x):** Fitting Software used to fit and program the Kanso 3 Sound Processor, and other sound processor manufactured by Cochlear Ltd. **Nucleus Smart App (Version 7.0.1.x):** Application for smart phones (Android and iOS platforms) used to control the sound processor settings, including volume, sensitivity, programs, and accessories.
Intended use of investigational medical device(s)	• The CP1170 sound processor is an unapproved investigational medical device. The sound processor is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The sound processor converts sounds into electrical signals, which it sends to the implant. The sound processor also provides power to the implant. • Custom Sound Pro (Version 7.0) fitting software is an approved medical device. The iteration of firmware required to program the investigational CP1170 sound processor (Version 7.0.x) is an unapproved investigational medical device. The fitting software is used in combination with other devices as part of a hearing implant system. It is intended to create and modify hearing profiles, to monitor the performance of the system and to facilitate firmware updates of the system. • Nucleus Smart App (Version 7.0) is an approved medical device. The iteration of firmware required for compatibility with the investigational CP1170 sound processor is an unapproved investigational device. The Nucleus Smart App is intended to be used as an accessory to other devices of a hearing implant system to monitor the performance of the system and to make adjustments to the sound processing unit.
Name and description of comparator device/product(s)	• Kanso 2 (CP1150) Sound Processor The Kanso 2 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 the implant. The processing unit also provides power to the implant.
Estimated recruitment period	3 months
Expected duration per subject	Up to 12 months
Number of subjects planned	20
Number of investigational sites planned	1

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); Freedom Series (CI24RE(CA), CI24RE(ST), CI422) or N24 Series (CIC3). 4. At least 6 months experience with a cochlear hearing implant 5. At least 3 months experience with any Nucleus sound processor and SCAN program 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 English as determined by the investigator 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, as determined by the Investigator. 6. Current participation, or participation in another interventional clinical study/trial in the past 30 days, involving an investigational drug or device (unless the other investigation was/is a Cochlear sponsored investigation and determined by the investigator or Sponsor to not impact this investigation).

Objectives and Endpoint	
Primary Objective	**Primary Endpoint**
To compare adult cochlear implant speech perception in spatially separated speech and noise (S0Nrearhalf) between the CP1170 sound processor programs, SCAN 2 FF (Automated ForwardFocus ON) and SCAN 2 (ForwardFocus OFF).	Paired difference in dB SRT (AuSTIN) between the CP1170 SCAN 2 FF (Automated ForwardFocus ON) and CP1170 SCAN 2 (ForwardFocus OFF), (65 dB SPL S0Nrearhalf 4TB).
Secondary Objective	**Secondary Endpoint**
To compare adult cochlear implant speech perception in spatially separated speech and noise (S0N3) between the CP1170 sound processor programs, SCAN 2 FF (Automated ForwardFocus ON) and SCAN 2 (ForwardFocus OFF).	Paired difference in dB SRT (AuSTIN) between the CP1170 SCAN 2 FF (ForwardFocus ON) and CP1170 SCAN 2 (ForwardFocus OFF), (65 dB SPL S0N3 Babble).
To evaluate adult cochlear implant speech perception in quiet with the CP1170 sound processor and the CP1150 sound processor (commercial version)	Paired difference in percentage CNC Words correct in quiet (50 dB) between the CP1170 sound processor and CP1150 sound processor (commercial version).
To compare subjective acceptance and satisfaction between the CP1170 sound processor and the subject's own processor.	Ratings based on the CP1170 Questionnaire after a minimum 2-weeks actual-use of the CP1170 sound processor in the home environment and the subject's own processor (Baseline Questionnaire).

To compare adult cochlear implant subjective hearing performance between the CP1170 sound processor and the subject's own processor.	Paired difference in Global SSQ12 scores after experience with the CP1170 sound processor and own processor (at baseline).
Exploratory Objectives	**Exploratory Endpoint**
To explore the feasibility of using an Ecological Momentary Assessment (EMA) application in an interventional study to obtain real-time responses from Cochlear implant users.	All real-time responses collected via the EMA application. Refer to Section 9.6.3 for further details.
To compare adult cochlear implant speech perception in spatially separated speech and noise (AuSTIN, 65 dB SPL S0Nrearhalf 4TB) between CP1170 microphone directionalities, SCAN 2 FF Zoom (Automated ForwardFocus ON) SCAN 2 FF Beam (Automated ForwardFocus ON).	Paired difference in dB SRT (AuSTIN, 65 dB SPL S0Nrearhalf 4TB) between the CP1170 SCAN 2 FF Zoom (Automated ForwardFocus ON) and CP1170 SCAN 2 FF Beam (Automated ForwardFocus ON) .
To compare adult cochlear implant speech perception in spatially separated speech and noise (AuSTIN, 65 dB SPL S0N3 Babble) between CP1170 microphone directionalities, SCAN 2 FF Zoom (Automated ForwardFocus ON) and SCAN 2 FF Beam (Automated ForwardFocus ON).	Paired difference in dB SRT (AuSTIN, 65 dB SPL S0N3 Babble) between the CP1170 SCAN 2 FF Zoom (Automated ForwardFocus ON) and CP1170 SCAN 2 FF Beam (Automated ForwardFocus ON).
To compare subjective acceptance and satisfaction between microphone directionalities: CP1170 sound processor using SCAN 2 FF Zoom and CP1170 sound processor using SCAN 2 FF Beam.	Ratings based on the CP1170 Questionnaire after a minimum 2-weeks actual-use of the CP1170 sound processor SCAN 2 FF Zoom and CP1170 sound processor SCAN 2 FF Beam.

3 Schedule of Events

Visit Type	**Screening**	**Visit 1[a]**	**Visit 2[b]**	**Ad Hoc[c]**	**EOS[d]**
Timing of Investigation	Day 0	Day 0	Week 2	NA	Month 12
Visit window (±)	NA	+ 7 days	+ 14 days	NA	± 30 days
Written informed consent	X				
Demographics	X				
Eligibility	X				
Hearing history	X				
Device history	X				
Medical history	X				
Baseline Questionnaire[e]		X			
SSQ12 - Own Processor[f]		X			
SSQ12 - CP1170 Sound Processor[g]				X	
APHAB Questionnaire				X	
CP1170 Fitting[h]		X		X	
Fitting optimisation[i]			X	X	
Speech perception testing - Speech in Noise[jk]				X	
Speech perception testing – Words in Quiet[l]				X	

[a] Screening and visit 1 may occur on the same day.

[b] Visit 2 signifies the end of the first take-home period. Procedures from Ad Hoc visits may be performed on the same day as required.

[c] Ad Hoc refers to any unscheduled visit and may be repeated.

[d] EOS can occur on the same day as an Ad Hoc visit.

[e] Information regarding the subject's own sound processor, i.e. that which they had been using prior to screening, and usage habits.

[f] Own processor is defined as the sound processor that the subject used for a minimum of 2 weeks prior to their enrolment.

[g] SSQ12 on the IMD following the final take-home period.

[h] First fitting of the investigational sound processor.

[i] Fitting optimisation is subject to need and may include programming changes, and hardware or firmware modifications or updates to the investigational sound processor.

[j] In-booth testing CP1170 SCAN 2 ForwardFocus ON compared with the CP1170 ForwardFocus OFF (65 dB SPL S0Nrearhalf 4-talker babble).

[k] CP1170 ForwardFocus ON (SCAN 2) and ForwardFocus OFF (SCAN 2) (65 dB SPL S0N3 babble).

[l] CNC words at 50dB SPL tested unilaterally.

Visit Type	**Screening**	**Visit 1[a]**	**Visit 2[b]**	**Ad Hoc[c]**	**EOS[d]**
Timing of Investigation	Day 0	Day 0	Week 2	NA	Month 12
Visit window (±)	NA	+ 7 days	+ 14 days	NA	± 30 days
Usability Assessment[m]				X	
CP1170 Questionnaire[n]				X	
EMA[o]				X	
Concomitant medications/therapies[p]	X	X	X	X	X
Adverse Events		X	X	X	X
Device Deficiencies		X	X	X	X
Device Exposure		X	X	X	X

Abbreviations: APHAB, Abbreviated Profile of Hearing Aid Benefit; EMA, Ecological Momentary Assessment; EOS, End of Study; SSQ12, Speech, Spatial and Qualities of Hearing scale;

[m] Acute usability interview to investigate usability and safety as part of usability engineering.

[n] Administered and repeated for a minimum of two take-home periods.

[o] EMA research mobile application eliciting timed feedback will be prescribed to subjects. Responses will be extracted by the investigator following completion of the take-home period where EMA was used.

[p] Prescription and/or over-the-counter medications.

4 BACKGROUND INFORMATION AND RATIONALE

4.1 Introduction

This clinical study aims to investigate actual-use usability and speech performance with the new Kanso 3 Sound Processor (Model: CP1170) and associated components, with particular focus on the acceptance of and satisfaction the automated noise reduction feature ForwardFocus in the Automatic Scene Classifier (SCAN), a feature to be commercially known as SCAN 2 FF.

This study will build on the evidence collected in previous studies on the Kanso 3 and Kanso 2 Sound Processors (see section 4.2.2) and will also aim to confirm the clinical performance of these.

4.2 Findings of Previous Nonclinical and Clinical Studies

4.2.1 Nonclinical Data

As outlined in Section 3.2 of the Kanso 3 Investigator's Brochure, safety and functional verification and validation testing have been performed on the Kanso 3 Sound Processor to demonstrate that the devices are safe for use in a clinical investigation.

4.2.2 Clinical Data

Clinical data relevant for the current investigation fall under two main categories: 1) evidence on the development and approval of ForwardFocus and 2) evidence on previous generations of OTE sound processors. These clinical data are summarized below.

4.2.2.1 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 Signal to Noise Ratio – Noise Reduction (SNR-NR) algorithm that was introduced in Nucleus 6 Sound Processor (CP910/CP920) 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 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 Speech, Spatial and Qualities (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 FF 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 FF were inferior to the baseline. Based on these findings the investigators recommended that FF 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 FF (strong, medium and mild) were found to be superior to the Nucleus 6 SCAN. For SWN presented behind the listener FF Strong was demonstrated to be superior to the Nucleus 6 SCAN. When speech and either SWN 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 Sound Processor 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 Sound Processor. 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 'SSQ of Hearing Scale' 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.

4.2.2.2 Clinical Data for OTE Sound Processors

The main relevant study with an OTE Sound Processor is the CLTD5754 study, the primary objective of this study was to determine the feasibility of ForwardFocus in an OTE configuration and the secondary objective was to collect formative usability information with prototype and early design versions of the Kanso 2 (CP1150) Sound Processor.

Twenty-two adult subjects underwent speech perception testing using Australian Speech Test In Noise (AuSTIN) adaptive sentences presented from the front with 4 talker babble noise from 90,180 & 270 degrees to the subject (S0N3). AuSTIN Speech Reception Threshold (SRT) data comparing ForwardFocus ON and ForwardFocus OFF demonstrated superiority with ForwardFocus ON (P=0.002, paired t-test).

The implementation of ForwardFocus in the CLTD5754 included the fixed microphone directionality Zoom and no automation. This evidence supported the approval of ForwardFocus with the Kanso 2 Sound Processor.

4.3 Study Rationale

This investigation is planned to investigate the performance and clinical benefits of features that are new to the Kanso 3 Sound Processor. This study will build on the evidence previously collected on OTE sound processors and ForwardFocus, with particular focus on the acceptance and satisfaction of the automation of ForwardFocus in the Kanso 3 Sound Processor, and the sound processor and associated components in general.

The key indicators of clinical performance and benefit include:

- AuSTIN Sentences in noise (hearing performance)
- Monosyllabic words in quiet (hearing performance)
- The subjective Speech and Spatial Qualities scores (as available)

5 MEDICAL DEVICE INFORMATION

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

5.1.1 Kanso 3 Sound Processor

5.1.1.1 Physical Description

The Kanso 3 OTE sound processor (Figure 1) to be used with a compatible hearing implant, is manufactured by Cochlear Limited. Kanso 3 is an incremental refinement of the previous generation, Kanso 2 Sound Processor, and reuses many of its existing technology and features with functional technology based on the Nucleus 8 Sound Processor (pending market approval).

The sound processor is worn on the head over the site of the compatible implant. They are held in place and aligned to the implant by magnets in the implant and sound processor. The Kanso 3 Sound Processor is a self-contained sound processor with the radio frequency (RF) coil, rechargeable battery and electronic components contained within one unit. The Kanso 3 Sound Processor user interface incorporates a three-colour LED indicator, with amber, blue and green LEDs, and an accelerometer that enables a tap interface.

Figure 1: External view of the Kanso 3 (CP1170) Sound Processor

5.1.1.2 Intended Use

The sound processor is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The sound processor converts sounds into electrical signals, which it sends to an implant. The sound processor also provides power to the implant.

5.1.1.3 Indications

5.1.1.3.1 Kanso 3 Sound Processor

Kanso 3 is indicated for a recipient with a compatible Cochlear Nucleus implant. The sound processor is compatible with the following Cochlear Nucleus implants:

- CI600 Series Implants[*]: CI612, CI622, CI624 and CI632
- CI500 Series Implants[†]: CI512, CI513, CI522, CI532, CI551 and ABI541
- CI24RE Series Implants: CI422, CI24RE (CA), CI24RE (ST), CI24RE (CS), CI24REH (Hybrid L24), CI8REH (Hybrid S8), CI12REH (Hybrid S12)
- CI24R Series Implants: CI24R (CS), CI24R (CA), CI24R (ST)
- CI24M Series Implants: CI24M, ABI24M, CI 11+11+2M, CI24MH (also known as CI 6+16+2M)

While the Kanso 3 Sound Processor is intended to be compatible and can be used with Hybrid implants they are not intended to provide acoustic stimulation.

5.1.2 Custom Sound Pro

The Kanso 3 Sound Processor can be programmed using the Custom Sound 7.x Software when it is connected to a programming computer via the Nucleus Freedom Programming Pod (PIF4) or Cochlear Wireless Programming Pod (PIF5.2). Custom Sound 7.x software is used to upgrade the sound processor firmware, as well as to configure the sound processor for the recipient, based on their hearing profile.

5.1.3 Nucleus Smart App

The Kanso 3 Sound Processor connects to compatible iOS devices (running iOS 12 or later) that support the Made for iPhone/iPod/iPad (MFi) Hearing Aid functionality via Bluetooth Low Energy. This enables basic control functions (program change, volume adjustment and audio source selection) and direct audio streaming from

[*] For Canada Only: CI632P are also indicated implants within the CI600 Series.

[†] For Canada Only: CI512P and CI532P are also indicated implants within the CI600 Series.

the iOS device (phone call, media audio and Live Listen). Kanso 3 Sound Processor also connects to compatible Android devices (running Android 10 or later) that support Audio Streaming for Hearing Aid (ASHA) functionality, via Bluetooth Low Energy. Compatibility with Android devices enables direct audio streaming capability from the Android device (phone call and media audio). Version 7.0.1.1006 and above enables new bimodal controls for subjects with a compatible mobile phone and bimodal configuration (compatible hearing aid on one ear and Cochlear hearing implant on the other ear). These features allow compatible users to change basic settings of their compatible hearing aid and cochlear implant simultaneously or separately, both within the Nucleus Smart App, where previously they may have been toggling between this and the ReSound mobile application.

The Kanso 3 Sound Processor is also able to connect to the Nucleus Smart App on Apple devices running iOS 10 or later, or Android devices running Android 5 or later, to access a full suite of control and monitoring functions.

5.2 Identity and Description of the Comparator

The Kanso 2 (Model Number: CP1150) is an OTE sound processor functionally based on the NEO-XS processing chip, which is used in the current commercially available BTE sound processor, Nucleus 7. Kanso 2 is smaller than Cochlear's first OTE sound processor, Kanso (CP950) and delivers additional connectivity and noise reduction functionalities.

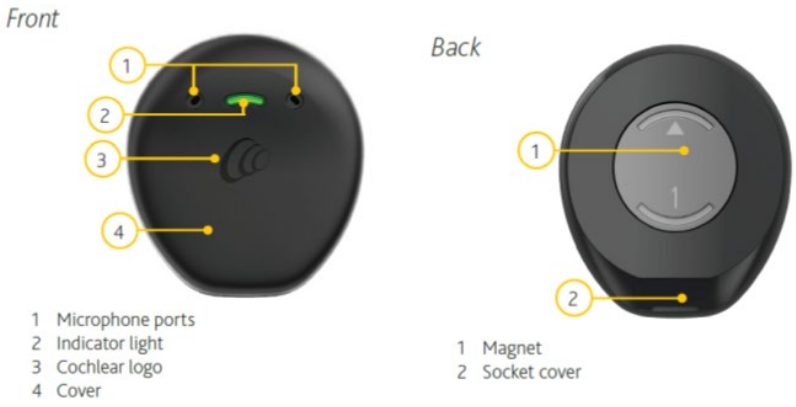

Figure 2. External views of the Kanso 2 (CP1150) Sound Processor

5.3 Accessory Device Requirements

5.3.1 Cochlear Home Charger

The Cochlear Home Charger is the primary charging device that will store, dry and charge a Kanso 2 and/or Kanso 3 Sound Processor.

5.3.2 Portable Charger

The Portable Charger can be used to charge the Kanso 2 and Kanso 3 Sound Processor on the go or when it is inconvenient for the subject to use a Home Charger. The Portable Charger also powers the sound processor as it is charging and contains an internal battery that requires charging before use. The Portable Charger battery takes approximately 3 hours to fully charge.

5.3.3 CR310 Remote Control

The CR310 Remote Control operates on a 2.4 GHz band and can be used to perform basic control functionality such as changing programs, adjusting loudness and selecting active audio sources.

5.3.4 Cochlear Wireless Accessories

Cochlear Wireless Accessories (Table 1) operates on a 2.4 GHz frequency band to deliver wireless audio streaming to Kanso 3 via the NXP2 Protocol. These optional accessories are designed to provide a consistent input level and an improved SNR ratio to overcome the effects of distance and competing noise in specific listening situations (classrooms, telephone conversations, TV viewing).

Table 1: Compatible Cochlear Wireless Accessories

Configuration	Compatible Wireless Accessory
Mini Microphone	Cochlear™ Wireless Mini Microphone, Cochlear™ Wireless Mini Microphone 2, Cochlear™ Wireless Mini Microphone 2+
TV Streamer	Cochlear™ Wireless TV Streamer
Phone Clip	Cochlear™ Wireless Phone Clip

Kanso 3 is also compatible with GN Resound TV Streamer and the GN Resound Mini Microphone, which are based on the Bluetooth 5.2 protocol.

5.3.5 iOS and Android Devices and the Nucleus Smart App

Kanso 3 connects to compatible iOS devices (running iOS 12 or later) that support the Made for iPhone/iPod/iPad (MFi) Hearing Aid functionality via Bluetooth Low Energy. This enables basic control functions (program change, volume adjustment and audio source selection) and direct audio streaming from the iOS device (phone call, media audio and Live Listen). Kanso 3 connects to compatible Android devices (running Android 10 or later) that support Audio Streaming for Hearing Aid (ASHA) functionality, via Bluetooth Low Energy. Compatibility with Android devices enables direct audio streaming capability from the Android device (phone call and media audio).

Kanso 3 is also able to connect to the Nucleus Smart App on Apple devices running iOS 10 or later or Android devices running Android 5 or later to access a full suite of control and monitoring functions.

5.3.6 Retention Accessories

For large skin flap thicknesses or for vigorous activity, retention aids may be necessary to ensure that, if the sound processor becomes detached from the implant magnet, it does not fall on the ground and be at risk of being damaged.

The following retention accessories are compatible with Kanso 3 Sound Processors:

- Headband
- Safety Line
- Kanso Halo Accessory

5.3.7 Aqua+

The Kanso 3 Sound Processor is compatible with a re-usable, sealable Aqua+ accessory that provides ingress protection up to IP68 during use in or around water (e.g. when swimming, surfing, showering etc.).

5.3.8 Cochlear SoftWear Pad

For a recipient who requires a high magnet strength, or who has a thin skin flap, the pressure imposed on their skin by the sound processor may lead to discomfort. The Cochlear SoftWear pad can be applied to the bottom of the sound processor to distribute the pressure imposed on the skin by the magnetic force over a wider area.

5.3.9 Chargers

The Home Charger is the primary charging unit for Kanso 3 Sound Processor and is the same as the charger currently available for Kanso 2. It integrates wireless charging capability with the ability to dry the Kanso 3 Sound Processor.

The Portable Charger is a portable, wearable charging option for the Kanso 2 and Kanso 3 Sound Processor, allowing recipients to have extended on-air time in situations where they require more charge than the integrated sound processor battery can provide.

5.3.10 Programming Adaptor Cable

The CP1150 Programming Adaptor Cable enables the Kanso 3 Sound Processor to be programmed, via connection to either a PIF4 or PIF5.2. When used with a PIF4 and a CP1000 Programming Cable, the Kanso 3 Sound Processor is powered by the PC. When used with a PIF5.2, the Kanso 3 Sound Processor is powered by the CP1000 Rechargeable Battery.

6 OBJECTIVES

6.1 Primary Objective

- To compare adult cochlear implant speech perception in spatially separated speech and noise (S0Nrearhalf) between the CP1170 sound processor programs, SCAN 2 FF (Automated ForwardFocus ON) and SCAN 2 (ForwardFocus OFF).

6.2 Secondary Objectives

1. To compare adult cochlear implant speech perception in spatially separated speech and noise (S0N3) between the CP1170 sound processor programs, SCAN 2 FF (Automated ForwardFocus ON) and SCAN 2 (ForwardFocus OFF).
2. To evaluate adult cochlear implant speech perception in quiet with the CP1170 sound processor and the CP1150 sound processor (commercial version).
3. To compare subjective acceptance and satisfaction between the CP1170 sound processor and the subject's own processor.
4. To compare adult cochlear implant subjective hearing performance between the CP1170 sound processor and the subject's own processor.

6.3 Exploratory Objectives

1. To explore the feasibility of using an Ecological Momentary Assessment (EMA) application in an interventional study to obtain real-time responses from Cochlear implant users.
2. To compare adult cochlear implant speech perception in spatially separated speech and noise (AuSTIN, 65 dB SPL S0Nrearhalf 4TB) between CP1170 microphone directionalities, SCAN 2 FF Zoom (Automated ForwardFocus ON) and SCAN 2 FF Beam (Automated ForwardFocus ON).
3. To compare adult cochlear implant speech perception in spatially separated speech and noise (AuSTIN, 65 dB SPL S0N3 Babble) between CP1170 microphone directionalities, SCAN 2 FF Zoom (Automated ForwardFocus ON) and SCAN 2 FF Beam (Automated ForwardFocus ON).
4. To compare subjective acceptance and satisfaction between microphone directionalities: CP1170 sound processor using SCAN 2 FF Zoom and CP1170 sound processor using SCAN 2 FF Beam.

7 DESIGN OF THE CLINICAL INVESTIGATION

7.1 General

This is a pre-market, prospective, single-site, open-label, within-subject, interventional study of acceptance and performance of the Kanso 3 Sound Processor (Model: CP1170) through actual-use with adult cochlear implant recipients. The IMD is the Kanso 3 Sound Processor, used in conjunction with the investigational version of Custom Sound Pro fitting software, investigational version of Nucleus Smart App. The comparators include acute use of the Kanso 2 Sound Processor (Model: CP1150) to compare performance in quiet and subject's own sound processor (i.e. any BTE or OTE which they entered the study with) to compare subjective performance and acceptance.

The subjects include adults aged 18 years and older who are currently using a Cochlear hearing implant. Subjects will be screened and 20 eligible subjects will be recruited in the clinical investigation from a single investigational site located in Australia. After enrolment, subjects will attend scheduled study visits for a period up to 12 months 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. All subjects will attend an end-of-study visit at the time they complete the study.

The primary endpoint is to determine the hearing performance of the Kanso 3 Sound Processor with the new implementation of ForwardFocus in SCAN 2 (SCAN 2 FF), as assessed by speech perception in noise. Safety will be assessed by recording and summarising all AEs/ADEs and DDs. No data monitoring committee will be used for this clinical investigation. All subjects will attend an End-of-Study visit at the time they complete the study.

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 controlled test environments. 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 at least 5 in-clinic visits with take home use between each visit. The test sessions will include speech perception tests including sentence in noise and words in quiet tests and may include the completion of questionnaires and usability assessment. 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. Participants will not be told which program will be used in which order, and due to the similar form factor of the sound processor generations, it may also be possible to conceal which sound processor 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.

Each take-home period will be a minimum of 2 weeks, allowing a period sufficient to represent a realistic test of the performance of the device and allow any risks associated with ADEs over that period to be identified and assessed. As per the adaptive procedure outlined in Section 6.3.3, should DDs occur resulting in the subject being unable to complete a minimum 2-week take home period, actual-use testing may be paused until the subject can return to the clinic to have the issue investigated and rectified.

7.2 Subjects

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

To maintain confidentiality, subject names will not be recorded on any study document other than the informed consent form and Subject ID Log; neither document will be provided to the Sponsor. All individuals who provide informed consent are considered enrolled into the study and will be assigned a unique identifier. If a subject signs consent and either exits the study or fails the screening assessments prior to initiating Visit 1, they will be considered a screen failure and will not be counted as part of the required 20 subjects for the study.

The subjects include adults aged 18 years or older with at least 3 months experience with a Cochlear 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.

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[‡]

[‡] Pre-lingually deafened subjects with adequate speech comprehension (as evidenced by compliance with inclusion criterion 6) are considered acceptable for enrolment.

3. Implanted with the CI600 Series (CI612, CI632, CI622, CI624), CI500 Series (CI512, CI532, CI522), Freedom Series (CI24RE(CA), CI24RE(ST), CI422), N24 Series (CIC3).[§]
4. At least 6 months experience with a cochlear hearing implant.
5. At least 3 months experience with any Nucleus sound processor and SCAN program.
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 English as determined by the investigator
9. 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, as determined by the Investigator.
6. Current participation, or participation in another interventional clinical study/trial in the past 30 days, involving an investigational drug or device (unless the other investigation was/is a Cochlear sponsored investigation and determined by the investigator or Sponsor to not impact this investigation).

7.2.3 Number of Subjects Required

A total of twenty subjects are to be recruited to meet the sample size calculation requirements (Section 9.4) with a dropout rate of no more than 15%.

7.2.4 Vulnerable Populations

Pregnant women will not be excluded from this study. 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 a signed the Informed Consent form for the study.

[§] All implant models considered acceptable for enrolment are listed in Section 5.1.1.3.1: Indications.

- 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.
- Discontinued: An Enrolled subject who withdrew consent, was discontinued by the Investigator or Sponsor before the expected End of Study visit, or lost to follow-up. Discontinued subjects may still have safety follow up data collection until their scheduled End of Study visit, for reasons described in section 7.2.6.
- Completed: Enrolled subjects who complete the required treatment and visit schedule.

The recruitment period for the clinical investigation is estimated to be up to 3 months 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 up to 12 months from the time of informed consent through to the End of Study visit.

Clinical Investigation completion is last subject last visit. In the event of an ongoing Serious Adverse Events (SAEs) or Serious Adverse Device Effects (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 and Procedures 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 electronic case report form (eCRF), if provided.

The Investigator or Sponsor may also decide to withdraw a subject from the clinical investigation or stop the use of the investigational device 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
- Other (specify)

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.

SRT S0Nrearhalf Test order

Primary: Kanso 3 SCAN 2 FF Zoom (Automated ForwardFocus ON) vs Kanso 3 SCAN 2 (ForwardFocus OFF)

Exploratory (2): Kanso 3 SCAN 2 FF Zoom (Automated ForwardFocus ON) vs Kanso 3 SCAN 2 FF Beam (Automated ForwardFocus ON)

Subjects will be tested in the following order:

Subject ID	1st	2nd	3rd
1, 7, 13, 19	SCAN 2 FF Zoom	SCAN 2 FF Beam	SCAN 2 (FF OFF)
2, 8, 14, 20	SCAN 2 (FF OFF)	SCAN 2 FF Zoom	SCAN 2 FF Beam
3, 9, 15	SCAN 2 FF Beam	SCAN 2 (FF OFF)	SCAN 2 FF Zoom
4, 10, 16	SCAN 2 FF Zoom	SCAN 2 (FF OFF)	SCAN 2 FF Beam
5, 11, 17	SCAN 2 FF Beam	SCAN 2 FF Zoom	SCAN 2 (FF OFF)
6, 12, 18	SCAN 2 (FF OFF)	SCAN 2 FF Beam	SCAN 2 FF Zoom

SRT S0N3 Test order

Secondary (1): Kanso 3 SCAN 2 FF Zoom (Automated ForwardFocus ON) vs Kanso 3 SCAN 2 (ForwardFocus OFF)

Exploratory (3): Kanso 3 SCAN 2 FF Zoom (Automated ForwardFocus ON) vs Kanso 3 SCAN 2 FF Beam (Automated ForwardFocus ON)

Subjects will be tested in the following order:

Subject ID	1st	2nd	3rd
1, 7, 13, 19	SCAN 2 FF Zoom	SCAN 2 FF Beam	SCAN 2 (FF OFF)
2, 8, 14, 20	SCAN 2 (FF OFF)	SCAN 2 FF Zoom	SCAN 2 FF Beam
3, 9, 15	SCAN 2 FF Beam	SCAN 2 (FF OFF)	SCAN 2 FF Zoom
4, 10, 16	SCAN 2 FF Zoom	SCAN 2 (FF OFF)	SCAN 2 FF Beam
5, 11, 17	SCAN 2 FF Beam	SCAN 2 FF Zoom	SCAN 2 (FF OFF)
6, 12, 18	SCAN 2 (FF OFF)	SCAN 2 FF Beam	SCAN 2 FF Zoom

CNC Words Test Order

Secondary (2): Kanso 3 (CP1170) vs Kanso 2 (CP1150)

Subjects assigned a study ID including ODD numbers (01, 03, 05 etc) will be tested in the following order:

1. Kanso 3
2. Kanso 2

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 procedures 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 and take-home periods, 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 Evaluations and Procedures

7.3.1 Screening/eligibility

- Screening and informed consent: Subjects must be consented to the study and inclusion and exclusion criteria confirmed prior to any study activities starting.
    - Evidence for inclusion criteria #6 (i.e. able to score 30% or more at +15 SNR with CI alone on a sentence in babble test) can be provided from data on file for subjects who had previously participated in clinical investigations at the site.
- Standard eCRFs will be completed, including:
    - Demographics: information about the subjects age and gender identification.
    - Eligibility: itemised confirmation that the subject meets all inclusion and exclusion criteria.
    - Medical history: information about any current or past medical conditions or surgical history.
    - Hearing history: information about the subject's hearing for both ears, including hearing loss, age of onset of initial hearing loss, hearing loss type, history of hearing loss, primary cause of hearing loss and other relevant aspects of the subject's audiological history.
    - Device history: information about the subject's cochlear implant and/or hearing aid usage and amplification history.
    - Concomitant medications/therapies: all prescription and/or over-the-counter medications as reported by the subject.

Screening and Visit 1 procedures may occur at the same visit.

7.3.1.1 Visit 1

- Baseline SSQ: *see Section 7.3.2.6.1.*
- Baseline Device Characteristics Questionnaire: *see Section 7.3.2.6.2.*
- CP1170 Fitting: *see Section 7.3.2.3*.

7.3.1.2 Visit 2

- Fitting optimisation (optional, as required): *see Section 7.3.2.4.*

Visit 2 and Ad Hoc Visit procedures may be conducted on the same day.

7.3.1.3 Ad Hoc Visits

Ad Hoc visits are not tied to any specific visit or timing window and may be repeated to perform any of the following procedures when appropriate, as determined by the investigator:

- Sound processor fitting to initiate a take-home period or fitting optimisation (optional, as required).
- Speech perception evaluations in noise (as required): *see section 7.3.2.1.*
- Speech perception evaluation quiet (as required): *see section 7.3.2.2*.
- Usability interview (as required): *see section 7.3.3.1.*

- Provision or collection of questionnaires, (e.g. the EMA, CP1170 and/or CP1170 Questionnaire; as required).
- If the ad-hoc visit is at the end of a take-home period, study subjects will be asked about their experience with the CP1170 sound processor. Device deficiencies and adverse events experienced during this take home period will be recorded if not already.

A maximum of 20 Ad-Hoc Visits is expected duration of the study.

7.3.1.4 End of Study Visit

- Collection of final SSQ12 Questionnaire following CP1170 use: *see Section 7.3.2.6.1.*
- Collection of any remaining questionnaires (e.g. EMA or CP1170 Questionnaire) provided as part of final take-home period (as required).
- Return devices and study completion: At the end of the study, subjects will return all IMDs and associated components and revert to full-time use of their own device with the commercially available firmware.

The EOS visit can occur on the same day as an Ad Hoc visit.

7.3.2 Performance/Effectiveness

Refer to the Schedule of Events in Section 3 for details of the timing and frequency of the evaluations described in the subsections below.

7.3.2.1 Speech perception in noise

Speech perception in noise will be measured using the Australian Speech Test In Noise (AUSTIN) (Dawson, Hersbach, & Swanson, 2013), which is a test that uses BKB like target sentences presented in adaptive noise. The goal of the speech perception test in noise is to provide the SNR for 50% speech intelligibility. The signal level will be fixed at 65 dB SPL. Sentence in noise tests will be measured using this procedure in the two speaker configurations shown below.

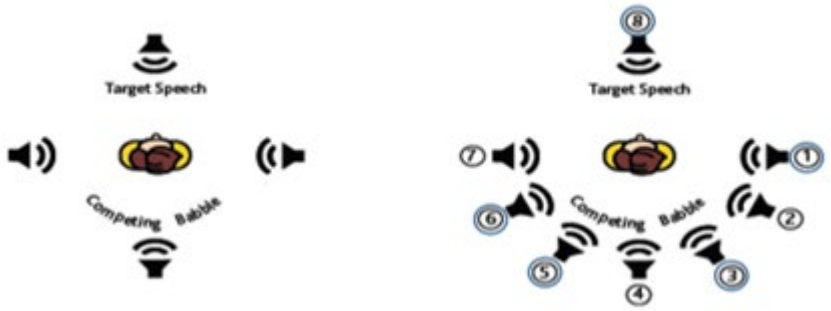

Figure 3. Left – S0N3 with babble noise from 90, 180 and 270 degrees (3 talkers in total). Right -S0Nrearhalf with roving babble noise presented from 4 speakers in the rear hemisphere (4 talkers in total). The rear hemisphere will consist of 7 speakers and the 4 noise speakers will change for every sentence in the test list.

In booth speech perception testing will be conducted using the signal processing combinations and hardware listed in Table 2. The order of testing will be conducted according to the counterbalancing outlined in Section 7.2.7.

Table 2. Speech in Noise test conditions (S0Nrearhalf and S0N3). Whisper, WNR, ADRO and ASC will be activated according to user preference.

#	Condition	SNR-NR	Sound Processing	Directionality	ForwardFocus	Comparisons
1	Kanso 3 SCAN 2 FF Zoom (Automated ForwardFocus ON)	✓	SCAN 2	Zoom	ON	Primary: 1 vs 3 in 65 dB SPL S0Nrearhalf 4TB. Secondary (1): 1 vs 3 in 65 dB SPL S0N3 Babble. Exploratory (2): 1 vs 2 in 65 dB SPL S0Nrearhalf 4TB. Exploratory (3): 1 vs 2 in S0N3 Babble
2	Kanso 3 SCAN 2 FF Beam (Automated ForwardFocus ON)	✓	SCAN 2	Beam	ON	
3	Kanso 3 SCAN 2 (ForwardFocus OFF)	✓	SCAN 2	Beam	OFF	

For S0Nrearhalf and S0N3 speech in noise tests, all subjects will be tested unilaterally. That is, unilateral subjects will have their contralateral ear (non-test ear) blocked with an earplug for all test conditions. Subjects with bilateral implants will be tested using the subject's preferred listening 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 AuSTIN software will be used to present the test material. 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 either:
    - S0Nrearhalf: 4 locations in the rear hemisphere. In the S0Nrearhemi condition, four independent interfering talkers are presented from four locations simultaneously, randomly chosen from seven speakers between 90 to 270 degrees in a rear hemi-field. The noise locations remained fixed for the duration of each sentence and changed two seconds before the next sentence is presented (at the same time as the noise level changed).
    - S0N3: 90, 180 and 270 (3 speakers in total)

At the beginning of the test session a practice run of 16 sentences 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. For signal processing parameters that are expected to produce highly variable results or large differences, a practice run may be required for each signal processing combination. The number of sentences will be 20 for all test runs.

The investigator will record the result on the worksheet and in the Electronic Data Capture (EDC) system.

7.3.2.2 Speech perception in quiet

Speech perception in quiet will be measured using the CNC monosyllabic words (Peterson & Lehiste, 1962) at 50 dB SPL from S0 position (Figure 4). There will be 2 lists per condition. The goal of speech perception assessment in quiet is to compare % words correct for each of the conditions.

Figure 4. Speaker configuration for CNC words in quiet

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 Section 7.2.7.

Table 3. Speech in Quiet test conditions. Whisper, WNR, ADRO and ASC will be activated according to user preference.

Condition	SNR-NR	Default	ForwardFocus
Kanso 3 (CP1170)	✓	SCAN 2	OFF
Kanso 2 (CP1150)	✓	SCAN	OFF

All subjects will be tested unilaterally i.e., unilateral subjects will have their contralateral ear (non-test ear) blocked with an earplug for all test conditions and subjects with bilateral implants will be tested using the subject's preferred listening 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 AuSTIN software will be used to present the test material. The investigator, or suitably qualified delegate will use the software to select:

- CNC word test
- 50 dB SPL presentation level
- Signal from in front (0 degrees)
- 2 lists of 50 words each

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

7.3.2.3 CP1170 Fitting

The CP1170 sound processor will be programmed with the subject's own hearing maps and custom programs allowing them to trial the new automated SCAN 2 FF program. The Investigator will set up all devices required for the subject's take-home use. This may include pairing to their own or loaner assistive listening devices,

fitting any retention accessories, installing the compatible Nucleus Smart App on subject's own or a loaner smartphone, and pairing the investigational processors to the subject's phone accordingly.

7.3.2.4 Fitting Optimisation

Fitting optimisation (optional, as required): Device optimisation including changes to signal processing features, MAP adjustments, issuance of new firmware and new features as made available throughout the course of the trial.

7.3.2.5 Take-Home Period(s)

Take-home periods refer to blocks of time where the subject will use the IMD and associated accessories as their full-time device for a minimum of 2 weeks. The purpose of this is to allow actual use in the home environment. Should the subject report DD(s) within this time (via provoked or unprovoked feedback), the take-home period may be paused or stopped, allowing subjects to return to using their own sound processor until the DD can be investigated or resolved. There will be at least one take-home period between Visit 1 and Visit 2 and may be repeated as part of Ad-Hoc Visits until EOS.

During take-home periods, all subjects will be provided with SCAN 2 FF (automated ForwardFocus ON) as Program 1, and a SCAN 2 (user-controlled ForwardFocus, no automation) as Program 2.

While there are no expected unplanned product changes, early product can be sensitive to the low-risk issues identified in Table 4. During this study these product issues may be identified by study subjects during the in-clinic 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 4 identifies how issues will be investigated and retested by the research subjects.

7.3.2.6 Subjective Ratings

7.3.2.6.1 Speech, Spatial and Qualities of Hearing Scale (SSQ12)

The SSQ is designed to measure a range of hearing disabilities across several domains. Subjects are asked to rate their ability to hear speech in a variety of competing contexts, subjects are also asked about their spatial hearing abilities including the impact of direction, distance and movement associated with spatial hearing. Subjects are also asked about their ease of listening, and the naturalness, clarity and identifiability of different speakers (Gatehouse & Noble, 2004; Noble, Jensen, Naylor, Bhullar, & Akeroyd, 2013). A shortened form of the 49-question SSQ, the SSQ12, will be used in this study.

Study subjects will be asked to complete the SSQ12 at two time points in the study; 1) at study entry, where scores will reflect their experience with their own sound processor, 2) after take home use with the Kanso 3 Sound Processor.

7.3.2.6.2 Baseline Questionnaire

The custom Baseline Questionnaire is designed to collect information regarding the subject's preferred sound processing strategies and usage characteristics prior to their study entry and based on their own sound processor and hearing experience.

7.3.2.6.3 CP1170 Questionnaire

The custom CP1170 Questionnaire to collect information regarding the subject's experience using the CP1170 sound processor as compared to the Baseline Questionnaire. The questionnaire will be administered for a minimum of 2 take-home periods, i.e., following the first take-home period and repeated to facilitate the investigation of the exploratory objective comparing Zoom and Beam directionality settings.

7.3.2.6.4 Abbreviated Profile of Hearing Aid Benefit (APHAB)

The APHAB (Cox & Alexander, 1995) is a validated questionnaire which produces scores to determine comparative benefits for a given patient. Permission was granted by The University of Memphis School of Communication Sciences & Disorders to modify the response columns to replace the unaided versus aided hearing aid comparison, with the comparison of two sound processor settings (e.g. Program 1 vs Program 2).

7.3.2.6.5 Ecological Momentary Assessment (EMA)

At the prescribed take-home period(s), subjects will be requested to respond to a series of questions on the Cochlear Research App. The EMA will elicit notifications to complete the survey (See *Appendix A*) up to 7 times daily on the subject's phone or loaned device for up to 8 days. EMA survey responses will be extracted by the investigator upon the subject's return to the clinic following the given take-home period(s).

7.3.2.7 Adaptive Procedure

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 formal testing will be paused for subjects while the change is made and a new version of the sound processor will be developed and issued to study participants. Investigators may proactively seek feedback during the subject's take-home period as a means to identify potential product issues, like those described in Table 4. All product issues will be recorded as Device Deficiencies. The IMD will be considered mature for speech perception testing when all product optimisations that impact on performance have been made.

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

Table 4. 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 Kanso 3 CP1170 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.

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.

7.3.3 Safety Evaluations and Procedures

The risks and anticipated ADEs for the Kanso 3 Sound Processor, 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 will be conducted by the Sponsor in accordance with the Sponsor's standard operating procedures.

7.3.3.1 Usability Assessments

Usability of the Kanso 3 Sound Processor may be assessed during study visits. All subjects will be asked to take part in a usability interview.

Study subjects may be asked to undertake typical tasks in a simulated use environment and the study investigators will observe the tasks and log any device deficiencies experienced during this time.

7.3.3.2 Concomitant Medication and Therapies

All prescription medications and over-the-counter medications, excluding vitamins and herbal supplements, will be collected as part of the study.

7.3.4 Procedural Mitigations (if required)

In the case of restriction to the subject's ability to visit the clinic, for example due to infectious disease isolation requirements, optional device programming and procedural provisions may be introduced. These measures are to support the continuation of this project, while ensuring the safety of subjects and study staff.

- Screening and consent: See Section 10 for the consent process. If a potential research candidate is temporarily restricted from attending the study site, screening and consent may be performed via

phone call or video conference. Paper copies of the consent form will be provided via mail/courier and subjects will be asked to use a prepaid envelope to return one original signed copy to the site.

- Device programming: Subjects may be asked to commence take-home testing through remote management. Devices, accessories, questionnaires, and instructions may be sent to subjects via courier, so that they do not need to attend the clinic. Prior to shipping, each subject's Kanso 3 sound processor(s) will be connected to the fitting software, Custom Sound Pro. The subject's MAP(s) from their own processor(s) are saved in their individual Custom Sound Pro file. This will be converted to their Kanso 3 sound processor MAP(s), and their preferred programs written to the study processor. If a subject's most recent MAP(s) are not retrievable either from the site's database or the subject's clinical audiologist, remote management will not be possible until they are able to attend the site to have their own processor(s) connected to the software. For subjects who do not wish to participate in remote study and device management, the device programming and fitting will be performed in clinic once they are able to attend.
- Usability interviews: Usability assessments may be conducted remotely to accommodate situations where test participants are unable to, or would prefer not to, travel to a site in order to perform testing. In the remote scenario, the usability interview will be conducted via video conferencing software. Subjects will be provided with all devices, accessories and user manuals required for the testing.
- Speech perception**:** Speech perception testing can only be conducted in-clinic. If restrictions are ongoing at the planned time of these study visits, these tests may be moved to later in the study. As such, speech perception tests have been decoupled from specific visits and are repeatable as part of the Ad Hoc visit(s). If time permits, and study subjects are willing, all speech perception tests may be conducted on the same day. All comparisons for a specific endpoint test will be completed on the same day.

7.4 Equipment Used for Evaluations and Procedures

7.4.1 Software

Speech testing in quiet and noise will be performed via the adaptive Australian Sentence Test in Noise (AuSTIN) test software (Dawson et al., 2013).

Devices and signal processing configurations will be programmed using Custom Sound 7.0.x

7.4.2 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 from the front and noise from 4 roving locations in the rear hemisphere (S0Nrearhalf) and with speech from in front and noise from 90-, 180- and 270-degrees azimuth (S0N3).

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.

7.5 Sponsor Role in Conduct of the Clinical Investigation

Sponsor and investigator roles are assumed by Cochlear employees.

This clinical investigation will be conducted by an internal site. Internal sites are clinical research facilities owned and operated by Cochlear. The internal site at Cochlear in Sydney consists 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, programming 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.

Activities to be performed by sponsor representative excluding monitoring include:

1. Application of clinical quality assurance and quality control principles to the processes of the clinical investigation
    a. Implement and maintain written clinical quality procedures to ensure the clinical investigation is designed, conducted and that data generated is compliant with the ISO 14155:2011 Standard (ISO, 2011).
    b. Clinical quality assurance and quality control will be implemented according to sponsors quality system (Cochlear Quality Manual reference [7])
2. Clinical investigation planning and conduct
    a. Selection of clinical personnel for project management of the clinical investigation
    b. Preparation of documents and materials for the clinical investigation
    c. Project management for the clinical investigation. i.e. accountability of investigational devices, clinical trial insurance coverage, submission of application(s) and investigation updates to the appropriate regulatory authority(ies).
3. Safety evaluation and reporting of adverse events (AE) to the TGA and ethics committee.
4. Clinical investigation close-out, statistical analyses and final report.

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

8.1 Anticipated Clinical Benefits

Direct benefits for individual participants include:

- The opportunity to access to the newest innovations before they are made available to the general public.
- The chance to play an active role in their own hearing health and gain a greater understanding of their condition.
- Advice, care, and support from trained clinical staff who understand hearing loss or their condition.

Due to the limited use of the IMD (at least monthly over a period of up to 12 months), there are no long-term clinical benefits anticipated for the subjects.

8.2 Anticipated Adverse Device Effects

Cochlear's internal hazards analysis considers probable hazardous situations relating to the IMD and comparator.

The risks associated with the Kanso 3, Kanso 2 and associated components 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 Kanso 2 and Kanso 3 Sound Processors, 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 Guides and relevant instructions for use. Adverse effects, warnings and contraindications are further described in the Section 4.5 and Section 5.2 of the Kanso 3 Investigator's Brochure.

8.3 Risks Associated with Participation in the Clinical Investigation

There is a risk that the programs on the investigational sound processor may sound different to the subject's own sound processor. 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. Possible interactions with concomitant medications and residual risks for the device are not anticipated in this clinical investigation.

8.4 Risk Mitigation

The study investigational devices have been tested for safety, and the performance and use of the device is expected to be similar to the commercially available predicate. 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.

- All investigators will receive training in the use and handling of the investigational sound processor as part of study initiation.
- All reported ADEs and DDs will be regularly reviewed by the Sponsor's Clinical Review Board for the duration of the study to facilitate early detection and appropriate intervention if events are unanticipated with respect to incidence, severity, or outcome.
- In cases where the sound becomes at all uncomfortable or uncomfortably loud during fitting, subjects are encouraged to remove the sound processor from their head or inform the investigator so that stimulation is immediately ceased.
- Should any discomfort occur during take-home use, subjects will be advised to remove the investigational sound processor and revert to using their own sound processor until the cause of the discomfort is understood and resolved.

8.5 Benefit-to Risk Rationale

The Kanso 3 Investigator's Brochure concludes that the clinical safety (risks) and performance benefit of devices relevant to anticipated performance of the device have been evaluated, and the data demonstrate that the device has a favourable safety profile and is effective. The hazards analyses, coupled with the design verification/validation and pre-clinical testing, establish that the anticipated benefits of the device outweigh the risks.

9 STATISTICAL CONSIDERATIONS

9.1 General Considerations

Continuous data will be summarised by the number of non-missing observations, the mean, median, the standard deviation, and the minimum and maximum values. Categorical data will be summarised by the number and percentage of subjects in each category. Confidence intervals will be two-sided and at the 95% confidence level. For the primary and secondary endpoints, these will be t-distribution based confidence intervals; normality of the data will be assessed.

All demographic and baseline characteristics collected on the subjects will be summarised. Subject disposition including reasons for withdrawal will also be summarised. All subject data will be included in subject data listings.

No adjustment of the significance level will be made for multiplicity of testing.

Missing data will not be imputed.

Should any deviations to the analyses outlined in this section arise, these deviations will be detailed in the statistical analysis plan.

9.2 Endpoints

9.2.1 Primary Endpoint

- Paired difference in dB SRT (AuSTIN) between the CP1170 SCAN 2 FF (Automated ForwardFocus ON) and CP1170 SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0Nrearhalf 4-talker-babble.

9.2.2 Secondary Endpoints

1. Paired difference in dB SRT (AuSTIN) between the CP1170 SCAN 2 FF (Automated ForwardFocus ON) and CP1170 SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0N3 babble.
2. Paired difference in percentage CNC Words correct in quiet (50 dB) with the CP1170 sound processor and CP1150 sound processor.
3. Ratings based on the CP1170 Questionnaire after a minimum 2-weeks actual-use of the CP1170 sound processor in the home environment and the subject's own processor (Baseline Questionnaire).
4. Paired difference in Global SSQ12 scores after experience with the CP1170 sound processor and own processor (baseline).

9.2.3 Exploratory Endpoints

1. All real-time responses collected in the EMA application. Refer Section 9.6.3 for further details.
2. Paired difference in dB SRT (AuSTIN, 65 dB SPL S0Nrearhalf 4TB) between the CP1170 SCAN 2 FF Zoom (Automated ForwardFocus ON) and CP1170 SCAN 2 FF Beam (Automated ForwardFocus ON) .
3. Paired difference in dB SRT (AuSTIN, 65 dB SPL S0N3 Babble) between the CP1170 SCAN 2 FF Zoom (Automated ForwardFocus ON) and CP1170 SCAN 2 FF Beam (Automated ForwardFocus ON) .
4. Ratings based on the CP1170 Questionnaire after a minimum 2-weeks actual-use of the CP1170 sound processor SCAN 2 FF Zoom and CP1170 sound processor SCAN 2 FF Beam.

9.3 Hypotheses

The population level summary of interest for each endpoint discussed in this section is the mean difference in the outcome (either speech outcomes or the Global SSQ12 score) between treatment and control (as defined separately for each hypothesis).

9.3.1 Primary Hypothesis

Endpoint: Paired difference in dB SRT (AuSTIN) between the CP1170 SCAN 2 FF (Automated ForwardFocus ON) and CP1170 SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0Nrearhalf 4-talker-babble. A non-inferiority margin of 1 dB is chosen based on clinical consensus.

H_0: Sentence in noise (S0Nrearhalf 4TB) scores (dB SRT) with the Kanso 3 with SCAN 2 FF ON (treatment) are inferior to those with the Kanso 3 with SCAN 2 (ForwardFocus OFF).

Kanso 3 *SCAN 2 FF ON* – Kanso 3 *SCAN 2 (*ForwardFocus OFF) *≥ 1 dB (NB: higher SRT scores represent poorer performance)*

H_1: Sentence in noise (S0Nrearhalf 4TB) scores (dB SRT) with the Kanso 3 with SCAN 2 FF ON (treatment) are inferior to those with the Kanso 3 with SCAN 2 (ForwardFocus OFF).

Kanso 3 *SCAN 2 FF ON* – Kanso 3 *SCAN 2 (ForwardFocus OFF)* < 1 dB

9.3.2 Secondary Hypotheses

Endpoint 1: Paired difference in dB SRT (AuSTIN) between CP1170 sound processor programs, SCAN 2 FF (Automated ForwardFocus ON) and SCAN 2 (ForwardFocus OFF). in 65 dB SPL S0N3 babble. A non-inferiority margin of 1 dB is chosen based on clinical consensus.

H_0: Sentence in noise (S0N3) scores (dB SRT) with the Kanso 3 with SCAN 2 FF (treatment) are inferior to those with the Kanso 3 with SCAN 2

Kanso 3 *SCAN 2 FF ON* – Kanso 3 *SCAN 2 (ForwardFocus OFF) ≥ 1 dB (NB: higher SRT scores represent poorer performance)*

H_1: Sentence in noise (S0N3scores (dB SRT) with the Kanso 3 with SCAN 2 FF ON (treatment) are inferior to those with the Kanso 3 with SCAN 2 (ForwardFocus OFF)

Kanso 3 *SCAN 2 FF ON* – Kanso 3 *SCAN 2 (ForwardFocus OFF)* < 1 dB

Endpoint 2: Paired difference in percentage CNC Words correct in quiet (50 dB) with the with the CP1170 sound processor (presented as Kanso 3 in the hypotheses) and the CP1150 sound processor (presented as Kanso 2 in the hypotheses). A non-inferiority margin of -10% is chosen based on clinical consensus.

H_0: Words in quiet (50 dB CNC words) scores (% words correct) with the Kanso 3 (treatment) are inferior to those with the Kanso 2.

CP1170 (Kanso 3) –CP1150 (Kanso 2) $\leq$ -10% *(NB: lower CNC words represent poorer performance)*

H_1: Words in quiet (50 dB CNC words) scores (% words correct) with the Kanso 3 (treatment) are non-inferior to those with the Kanso 2.

CP1170 (Kanso 3) – CP1150 (Kanso 2) > -10%

Endpoint 3: Paired difference in Global SSQ12 scores after experience with the Kanso 3. CP1170 Sound Processor (presented as Kanso 3 in the hypotheses) compared with the subject's own processor. A non-inferiority margin of -1 is chosen based on clinical consensus.

H_0: Hearing performance ratings (SSQ12) with the CP1110 Sound Processor (treatment) are inferior to those with subject's own processor (control)

Kanso 3 – Own Processor ≤ -1 *(NB: lower scores represent poorer performance)*

H_1: Hearing performance ratings (SSQ12) with the CP1110 Sound Processor (treatment) are non-inferior to those with subject's own processor (control)

Kanso 3 – Own Processor > -1

No formal hypotheses are specified for the following secondary endpoint:

- Ratings on the CP1170 Questionnaire.

9.3.3 Exploratory Hypothesis

There are no exploratory hypotheses.

9.4 Sample Size Determination

This is a non-inferiority study, and the sample size calculation was based on a non-inferiority test for SRT (Speech Recognition Threshold) scores (Kanso 3 Sound Processor with SCAN 2 FF compared to Kanso 3 Sound Processor with SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0Nrearhalf 4TB).

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

- A non-inferiority margin of 1 dB SRT. This margin is based on clinical consensus. NB: *higher SRT scores represent poorer performance*.

- A standard deviation (SD) of 1.36 dB for the difference (in scores). This SD is calculated from 256 paired differences and is an indicative test re-test SD for both S0Nrearhalf and S0N3.
- A significance level $\alpha = 0.025$ (one-tailed).
- A desired power of 0.8.

Based on these assumptions, a sample size of 17 is required to reject the null hypotheses of inferiority using a confidence interval method (one-tailed 97.5% confidence interval). Allowing for up to 15% attrition, a sample size of 20 subjects is planned for this study.

9.5 Analysis Populations

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

For cases in which the Intent-to-Treat (ITT) and PP populations lead to the same conclusions and 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 Clinical Investigation Report.

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

Intent-to-Treat Population

The ITT Population will include all subjects who consented and participated (refer Section 7.2.5).

For the purposes of the analyses of the primary and secondary endpoints, subjects will be included in the analysis regardless of protocol deviations. Missing data will not be imputed. Consequently, only subjects with paired treatment and control measurements will contribute to the analysis.

Per Protocol Population

The PP will include all subjects who have one set of paired measurements from treatment and control (for speech outcomes or SSQ12), without major protocol deviations. Major deviations will be defined at the clean file meeting before database lock. Treatment administration not conducted in the intended counterbalanced order of presentation will also be regarded as a protocol violation. However, it is expected that the sequence and period effects are minimal in this study, if any.

This analysis set will be the primary analysis set for the testing of non-inferiority (primary and secondary hypotheses).

Safety Population

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

9.6 Endpoint Analyses

All primary and secondary endpoint data will be presented as descriptive summaries and in subject data listings. Where appropriate, graphical presentations of these summaries will also be provided.

9.6.1 Primary Endpoint Analyses

For the non-inferiority test of SRT sentence scores (Kanso 3 with SCAN 2 FF ON versus Kanso 3 with SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0Nrearhalf 4TB), 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 below 1 dB, the treatment condition is regarded as non-inferior to the control in terms of SRT sentence perception. The non-inferiority margin of 1 dB for SRT is based on clinical consensus.

The primary testing of non-inferiority will be conducted for the PP analysis set. If non-inferiority is demonstrated, the testing will proceed to a test of superiority in the ITT analysis set.

9.6.2 Secondary Endpoint Analyses

As with the primary endpoint, the non-inferiority testing of the secondary endpoints will also be conducted in the PP analysis set. If non-inferiority is demonstrated, the testing will proceed a test of superiority in the IIT analysis set.

For the non-inferiority test of SRT sentence scores (Kanso 3 with SCAN 2 FF ON versus Kanso 3 with SCAN 2 (ForwardFocus OFF) in 65 dB SPL S0N3), 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 below 1 dB, the treatment condition is regarded as non-inferior to the control in terms of SRT sentence perception. The non-inferiority margin of 1 dB for SRT is based on clinical consensus.

For the non-inferiority test of CNC words in quiet scores (monosyllables), 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 terms of words in quiet perception. The non-inferiority margin of -10% for words in quiet scores (monosyllables) is also based on clinical consensus.

For the non-inferiority test of Global SSQ12 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 -1, the treatment condition is regarded as non-inferior to the control.

Data from the other questionnaires including the results for individual questions on the SSQ will be summarised descriptively. Qualitative data will be summarised as appropriate.

9.6.3 Exploratory Endpoint Analysis

Descriptive summaries on subject compliance with the EMA mobile application and their responses will be presented. Compliance will be analysed according to how many times the subject completed or partially completed the real-time questionnaire as prescribed. Historical data, exported by the app, may be searched and summarised according to patterns in the subjective responses. Qualitative results will be summarised in the report.

There are no formal hypotheses planned for the exploratory endpoints relating to the investigation of speech perception (AuSTIN) in noise between CP1170 microphone directionalities, SCAN 2 FF (Automated ForwardFocus ON) with Zoom and SCAN 2 FF with Beam (Automated ForwardFocus ON) under the two different noise conditions, 65 dB SPL S0Nrearhalf 4TB and 65 dB SPL S0N3 Babble. These comparisons will be presented descriptively together with 95% interval estimates for the mean paired differences. No inferences will be made.

9.7 Safety Analyses

For AE/ADEs and DDs, the percentage of subjects who experienced at least one event related to the IMD will be summarised. 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.

9.8 Interim Analyses

An analysis is planned on the following questionnaires after the completion of at least 1 take-home period where these were administered to all subjects:

- Primary Endpoint (See Section 9.2.1)
- Secondary Endpoint 1 (See Section 9.2.2)
- Baseline Questionnaire (See Section 9.2.2)
- CP1170 Questionnaire (See Section 9.2.2) following Take-Home period using SCAN 2 FF+ZoomCP1170 Questionnaire (See Section 9.2.2) following Take-Home period using SCAN 2 FF+Beam
- Exploratory Endpoint 2 (See Section 9.2.3)
- Exploratory Endpoint 3 (See Section 9.2.3)

The primary endpoint will be analysed at this interim analysis (test of non-inferiority). This will be the first and final analysis of the primary endpoint. The results of these analyses are not intended to stop the study or change the conduct of the remainder of the trial nor the collection and reporting of the data. Endpoints not reported at the interim analysis will be reported at the conclusion of the follow-up.

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 benefits and risks, what participation will involve, and established alternatives to participation will be explained to the subject in native non-technical language, understandable 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. They shall not waive or appear to waive their legal rights.

Each subject (or their legally designated representative) and the person who conducted the informed consent discussion, shall sign and personally date the Informed Consent Form (ICF). Where required, an independent and impartial 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.

This process shall be documented in the subject's source documents.

The subject, or the subject's legally designated 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.

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, and whether anticipated or unanticipated.

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 the use of 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.

NOTE 3: This includes 'comparator' if the comparator is a medical device.

11.1.3 Serious Adverse Event

A serious adverse event (SAE) is any AE that led to any of the following:

1) death,
2) serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:

- a life-threatening illness or injury, or
- a permanent impairment of, or damage to, a body structure or a body function including chronic diseases, 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,

3) foetal distress, foetal death or a congenital physical or mental abnormality, or birth defect including physical or mental impairment.

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 Investigator's Brochure.

NOTE: An anticipated serious adverse device effect is an effect, which by its nature, incidence, severity, or outcome has been identified in the Investigator's Brochure.

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, usability, safety, or performance.

NOTE 1: Device Deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

NOTE 2: This definition includes device deficiencies related to the IMD or the comparator.

11.1.8 Serious Health Threat

A signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subjects, users or other persons.

NOTE: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.

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/contact with the investigational sound processor and/or comparator. AE recording will continue for each subject until completion of their End of Study visit. Ongoing SAEs, 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 eCRF.

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 eCRF 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 product will be considered and investigated. The causal relationship to the IMD 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 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 and/or the Investigator's Brochure 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;

1) suitable action had not been taken,

2) intervention had not been made, or,

3) circumstances had been less fortunate

All DDs will be documented in the source notes and the DD page of the eCRF. All unapproved IMDs will be returned to the R&D Project Manager for device analysis either during the study for immediate investigation of any DD or at study-close out.

11.4 Reporting Responsibilities

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

11.4.1 Investigator Reporting of Serious Adverse Events

All AEs meeting the criteria for an SAE, or DD that could have led to a SADE must be reported to the Sponsor within 5 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, and shall conduct an expedited assessment of all SAEs, unanticipated ADEs, DDs that could have led to a SADE, including serious health threat.

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. Country specific sponsor reporting responsibilities are outlined in the Sponsor's Safety Data Handling Plan.

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

Name Sponsor Safety Monitor:	Clinical Review Board
Country:	Australia
Phone number:	NA
E-mail:	cltd-safetymonitor@cochlear.com

11.5 Independent Data Monitoring Committee

An IDMC is not required as the study is considered to be low risk according to the clinical study risk assessment.

12 DEVICE ACCOUNTABILITY

Supply of investigational medical devices will be recorded using the Sponsor Device Tracking Form (1295388) and Software Tracking Form (1302326). 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 Individual Subject Device Accountability Log Form (1295295).

At the end of the clinical investigation, all unused investigational medical devices shall be returned to the Sponsor.

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

14.1 Source Data

Source data will be captured in clinic notes, paper-based source data worksheets, or printed directly from testing software and entered into the eCRF. Questionnaire responses collected by the EMA research mobile application will be exported by the investigator, pseudo-anonymised according to subject ID and stored in a secure network drive. This data will not be entered directly into the eCRF. If electronic medical records do not permit read only access for monitoring purposes, a certified printout must be provided, indicated by a dated signature by a member of the site team or generated through a validated process.

An Origin of Source Data Form will be used to capture the location of source data kept at each site, outlining the individual site's process for certification.

14.2 Methods for Data Entry and Collection

Data collection will be performed using Medidata Rave for 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.

Medidata Rave 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.

14.3 Database Lock

At the conclusion of the study, the Study Data Manager in consultation with the Clinical Project Manager shall confirm that:

- No further subject visits will be conducted.
- All required forms have been completed in the EDC.
- All required data, including resolution to ongoing Adverse Events in accordance with CIP requirements, have been entered into the EDC.
- All required monitoring, including review of clinical data and Source Document Verification (SDV) according to the Monitoring Plan, has been performed.
- All data queries have been closed.
- All completed eCRFs have been signed by the Principal Investigator or delegate.

- The Statistical Analysis Plan (SAP) is final.
- The Clean File Meeting has been conducted.

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 eCRFs or related documents (for example, questionnaires). Subjects will be identified on eCRFs 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 eCRFs 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

This clinical investigation will be conducted under the Clinical Trial Notification (CTN) regulatory pathway.

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

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 10 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 on the public clinical trial registry, ClinicalTrials.gov.

A joint peer-reviewed publication authored by the clinical investigator(s) and Sponsor will be prepared. Furthermore, the results of the clinical investigation may also be disseminated as conference presentations (for example, abstract and poster session). Manuscript authorship and responsibilities will be discussed and agreed upon prior to investigation start and in accordance with guidelines and recommendations provided by the International Committee of Medical Journal Editors (ICMJE) to enable communication within 12 months of the Clinical Investigation Report (CIR) approval. 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, International Standard ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good Clinical Practice, 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 for the sponsor to follow, describing all the activities performed during site initiation, monitoring, and close out.

In accordance with applicable regulations, GCP, and sponsor's/CRO's procedures, monitors will contact the site prior to the start of the study to review with the site staff the CIP, study requirements, and their responsibilities to satisfy regulatory, ethical, and sponsor's requirements. When reviewing data collection procedures, the discussion will also include identification and documentation of source data items.

The sponsor/designee will monitor the site activity to verify that the:

- Data are authentic, accurate and complete
- Safety and rights of subjects are being protected
- Study is conducted in accordance with the currently approved CIP
- Any other study agreements, GCP, and all applicable regulatory requirements are met.

The investigator and the head of the medical institution (where applicable) agrees to allow the monitor direct access to all relevant documents.

22.2 Audits

To ensure compliance with GCP, the CIP, study procedures and applicable regulatory and EC requirements, an independent audit of the study may be conducted. The investigator/institution will be informed of the outcome for audits involving their site.

In addition, inspections by regulatory health authority representatives and EC(s) are possible. 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, for the purposes of a Sponsor audit of the site, or in preparation for an inspection.

Audits and inspections may occur at any time during or after completion of the study.

23 TRADEMARKS AND COPYRIGHT

24 REFERENCES

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10. World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2013. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

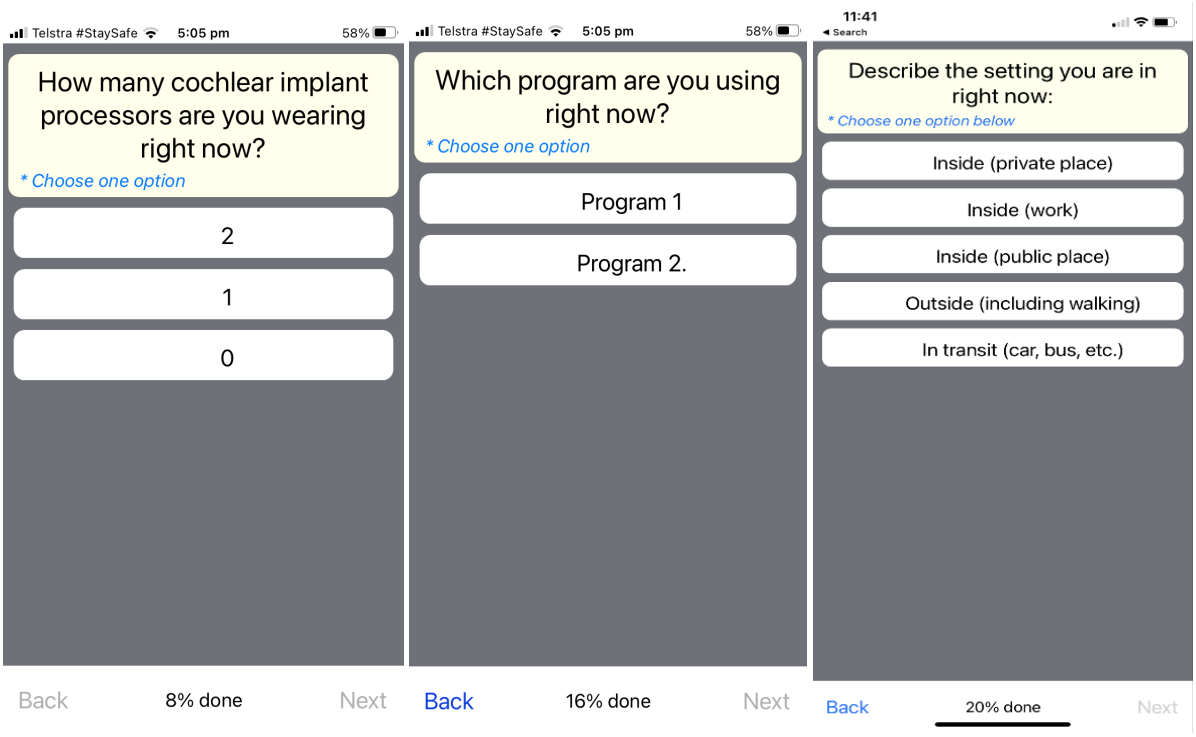
25 CHANGE HISTORY

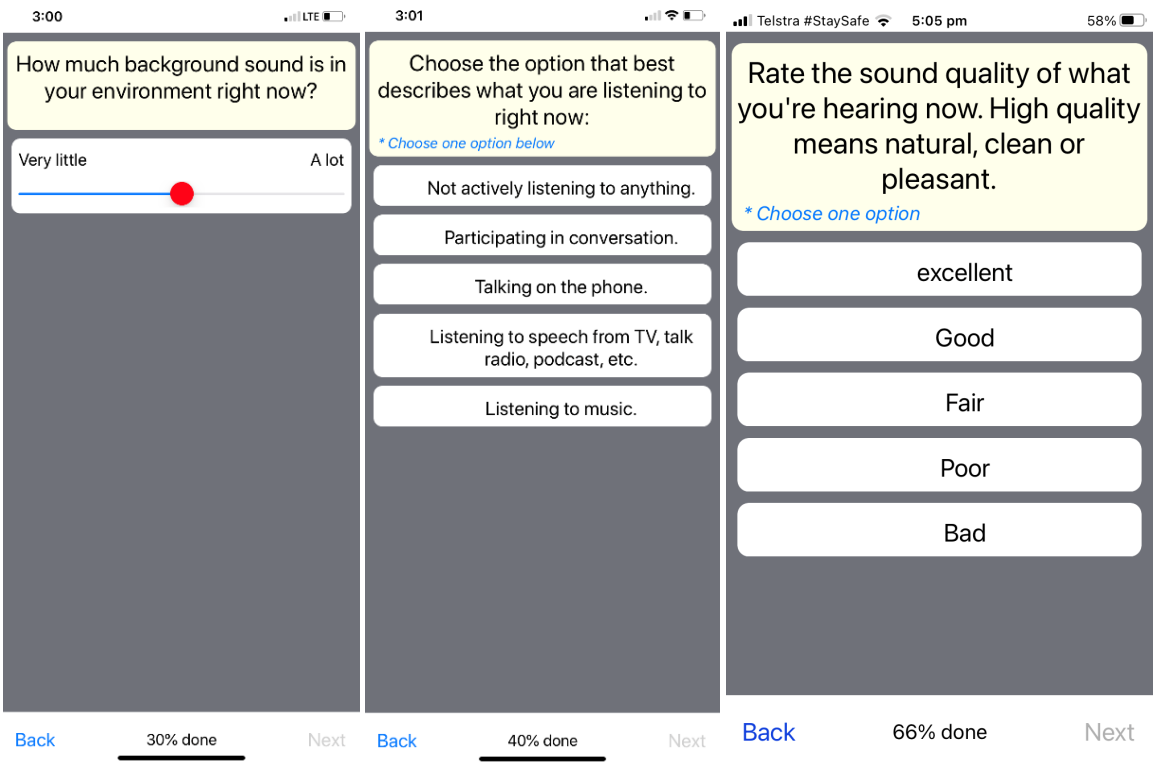
Version	Change	Rationale
1	Initial Release	NA
2	1. Added statement about t-distribution to General Statistical Considerations (Section 9.1). 2. Corrected errors in Schedule of Events (Section 3): • CP1170 Questionnaire changed from EOS to Ad Hoc visit • SSQ CP1170 Questionnaire moved from EOS to Ad Hoc visit • Added APHAB questionnaire • Removed (-) from Visit Window for visits 1 and 2 3. Added information about the APHAB Questionnaire to Section 7.3.2.6.4. 4. Corrected contradicting statement in Section 7.3.2.2, i.e., for the CNC words in quiet testing, all subjects (including bilaterally implanted subjects) will be tested unilaterally.	1. The statement will support the statistical analyses. 2. Edited to capture accurate procedures in Schedule of Events. 3. General information about the questionnaire was missing. 4. Corrected for accuracy and clarity around test procedure.
3	1. Site name on page 2 changed from Cochlear Sydney to Cochlear Headquarters. 2. Added exploratory objective (2) comparing microphone directionality settings in S0Nrearhalf configuration (Section 6.3 and Synopsis). 3. Added exploratory objective (3) comparing microphone directionality settings in S0N3 configuration (Section 6.3 and Synopsis). 4. Added exploratory objective (4) comparing subjective ratings between microphone directionality settings after periods of actual-use. 5. Fixed header row repetition in Schedule of Events table (Section 3). 6. Added footnote to CP1170 Questionnaire in Schedule of Events table (Section 3). 7. Added information about Bimodal controls in Nucleus Smart App (Section 5.2). 8. Changed bullets to numbering for secondary and exploratory objectives and endpoints from Section 6 onwards. 9. Added footnote to Inclusion Criteria #2 in Section 7.2.1.	1. Corrected for accuracy. 2. To gather exploratory data comparing directionality settings Zoom versus Beam in S0Nrearhalf. 3. To gather exploratory data comparing directionality settings Zoom versus Beam in S0N3. 4. To gather subjective exploratory data comparing microphone directionality settings: Zoom versus Beam. 5. Fixed bug in table formatting. 6. Corrected for accuracy and procedural clarity. 7. Bimodal features released for bimodal subjects as part of Nucleus Smart App V7.0.1.1006 onwards. Notification to EC acknowledged. 8. Clarity in referring to endpoints and respective comparisons. 9. Criterion included in error. Minimum speech perception inclusion criterion (5) outweighs age of initial hearing loss. Notification to EC acknowledged. At the time of CIP amendment, all subjects had been recruited. Therefore, the criterion was not removed retrospectively, and clarification added in the footnote.

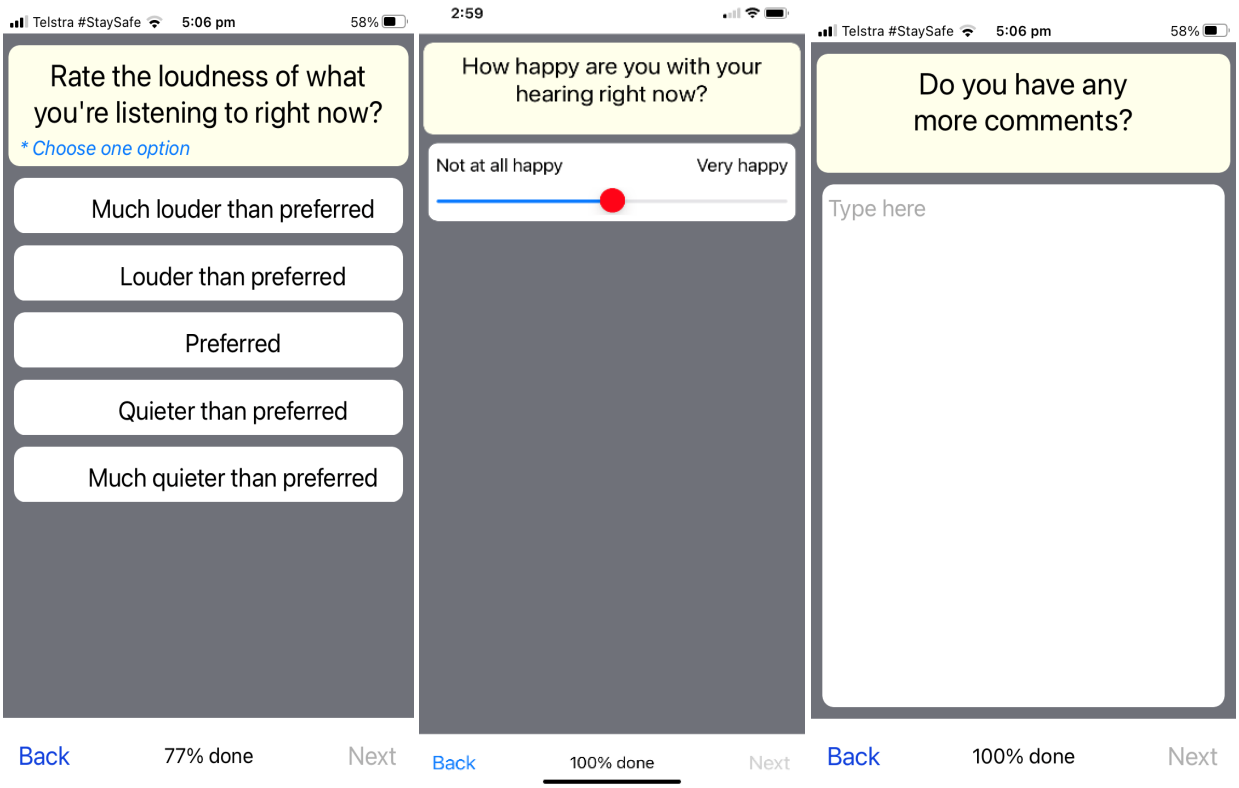
Version	Change	Rationale
	10. Added footnote to Inclusion Criteria #3 in Section 7.2.1. 11. Amended randomisation requirements in Section 7.2.7. 12. Adjusted Table 2 (Section 7.3.2.1) speech-in-noise test conditions. 13. Changed speech-in-noise test condition from preferred listening condition to unilateral testing only for all subjects (Section 7.3.2.1). 14. Added roving noise timing information for S0Nrearhalf (Section 7.3.2.1). 15. Added SCAN 2 column and deleted Directionality column in Table 3 (Section 7.3.2.2). 16. Added Program settings for take-home periods (Section 7.3.2.5). 17. Adjusted procedure wording for CP1170 Questionnaire (Section 7.3.2.6.3). 18. Added paragraph to Exploratory Hypotheses (Section 9.3.3). 19. Added the primary, secondary and exploratory endpoints 2 and 3 to Interim Analysis (Section 9.8). 20. Fixed header from page 27 onwards.	10. Correction of administrative error. All indicated implant types are listed in Section 5.1.1.3.1. Notification to EC acknowledged. At the time of CIP amendment, all subjects had been recruited. Therefore, the criterion was not removed retrospectively, and clarification added in the footnote. 11. Addition of exploratory hypotheses requires an additional condition to be tested during the speech-in-noise testing. As such, tables with updated permutations have been provided. 12. Adjusted to reflect new exploratory objective and clarification of comparisons required for respective endpoints. 13. Amended for accuracy. To control for variability in sub-populations (i.e. bilateral and unilateral). 14. Information was not available during initial CIP development. 15. No change to intended test conditions. Adjusted for accuracy and to minimise potential programming confusion. 16. Added detail for procedural accuracy. 17. Addition of exploratory objective (4) requires planned repeat of the CP1170 questionnaire to gather subjective feedback following take-home use of the microphone directionality settings, Zoom versus Beam. 18. Hypothesis details amended due to addition of exploratory objectives 2 and 3. 19. Internal product development timelines shifted, meaning that data will be collected and available at planned interim timepoint. 20. Header consistency throughout document.

APPENDIX A: ECOLOGICAL MOMENTARY ASSESSMENT (EMA)

This section shows screenshots from the EMA mobile research application.






Telstra #StaySafe 5:06 pm 58%
Rate the loudness of what you're listening to right now?
* Choose one option
Much louder than preferred
Louder than preferred
Preferred
Quieter than preferred
Much quieter than preferred
Back
77% done
Next
2:59
How happy are you with your hearing right now?
Not at all happy
Very happy
Back
100% done
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Do you have any more comments?
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