Clinical Investigation Plan

Usability of the CP950 sound processor with experienced cochlear implant users.

January 15, 2016

Study Sponsor:

Cochlear Americas
13059 E. Peakview Avenue
Centennial, CO 80111

Investigator Responsibilities

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, "**Usability of the CP950 sound processor with experienced cochlear implant users.**

Clinical Investigational Site
Primary Investigator's Name (print)
Title
Signature
Sponsor Representative
Title
Signature

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1. Clinical Investigation Synopsis

Investigation title	Usability of the CP950 sound processor with experienced cochlear implant users.
Name of investigational device	CP950 Sound processor CP950 Programming Cable Adaptor Cochlear Wireless Programming Pod
Total expected duration of the clinical investigation	6 months
Enrollment period	3 months
Expected duration per subject	1 Month post CP950 Fitting
Investigational design	Single-subject usability study
Number of subjects	Up to 30 subjects
Number of investigational sites	Up to 3 sites
Inclusion criteria	1. At least 6 months experience with a Nucleus 24 series or later implant in at least one implanted ear 2. Subjects age 12 and older who are cognitively and developmentally able to complete all study related questionnaires as deemed by the principal investigator or delegated staff 3. At least 3 months experience with the CP810,CP920 or CP910 sound processor 4. Ability to use 2 zinc air batteries with their current MAP 5. Willingness to participate in and to comply with all requirements of the protocol for the duration of the trial
Exclusion criteria	1. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedure and prosthetic device 2. Additional disabilities that would prevent participation in evaluations 3. Implant types not currently supported by the

	CP950 sound processor (i.e.,N22)		
Primary objectives	To evaluate usability of the CP950 sound processor using the CP950 Take Home Questionnaire for existing cochlear implant users. Specifically: 1) Patient Reported Hearing Performance 2) Retention & Comfort 3) Ease of use 4) Use of remote controls 5) Look & feel 6) Reliability 7) Maintenance & use		
Additional Information	To characterize CP950 sound processor field use data collected via Datalogging To evaluate the success of wireless pairing to both the wireless programming pod and wireless accessories		
Investigation schedule		**Visit 1**	**Visit 2**
	Subject Enrollment & Informed Consent	X	
	CP950 Fitting & Programming	X	X (Datalogs)
	Fit Wireless Accessories	X	
	CP950 Take Home Questionnaire - Subject		X
	Return of the CP950 Sound Processor		X
Primary endpoints	Patient reported satisfaction of the CP950 sound processor as measured by the CP950 Take Home Questionnaire for existing cochlear implant users. Areas of assessment:		

	1) Patient Reported Hearing Performance 2) Retention & Comfort 3) Ease of use 4) Use of remote controls 5) Look & feel 6) Reliability 7) Maintenance & use
Additional Information	Field use data including time on air, listening environment type, and accessory use will be described. The success/failure rate of wireless pairing to both the wireless programming pod and the remote microphone accessory will be quantified.

2. Abbreviations

Term	Definition
AE	Adverse Event
CRF	Case Report Form
IA	Initial Activation
IRB	Institutional Review Board
SAE	Serious Adverse Event

3. Introduction

Cochlear Limited's current commercial system is the Nucleus 6 (N6). This is comprised of external behind the ear (BTE) sound processors (CP910 and CP920) offering new input processing algorithms designed to improve recipients' hearing in specific situations, including background noise. The sound processors are controlled by either the remote assistant (CR230) or remote control (CR210) which avoids the user having to physically touch the sound processor. Clinicians are able to program the Nucleus 6 devices with Custom Sound 4 clinical software through either the Wireless Programming Pod or the traditional programming cable.

The CP950 Sound Processor functionality is comparable to the commercially approved Nucleus CP920 Sound Processor but in an off the ear (OTE) configuration. The processing unit, coil and magnet are integrated into one unit which is positioned directly over the magnet of the cochlear implant rather than behind the ear. The CP950 sound processor is designed to provide the same access to N6 technology including the CR210 Remote Control, the CR230 Remote Assistant as well as being compatible with the Cochlear Wireless Accessories.

Figure 1. CP950 Sound Processor

While the CP950 Sound Processor maintains the functionality of the CP920 Sound Processor, there have been a few modifications to support the OTE configuration:

- The CP950 Sound Processor only has one button while the CP920 Sound Processor has two. The ability to change volume and sensitivity for the CP950 Sound Processor will be available via either the CR230 remote assistant or CR210 remote control.
- Depending upon whether the CP950 Sound Processor is worn on the left (L) or right (R) sides of the recipients head the front and back microphones associated with wearing condition (R vs L) will need to be defined.
- As the batteries are integrated into the body of the CP950 Sound Processor they remain connected to the device when the programming cable is attached. During programming using the traditional wired Programming Pod, both the CP920 and CP950 Sound Processors are powered by the programming computer. Alternatively, due to the integrated batteries of the CP950 design, the sound processor may also be programmed via a Cochlear Wireless Programming Pod.

The primary objective of this study is to evaluate usability of the CP950 sound processor using the CP950 Take Home Questionnaire for existing cochlear implant users, specifically with regards to patient reported hearing performance, retention & comfort, ease of use, remote control use, look & feel, reliability and maintenance & use. The CP950 sound processor may provide added comfort and ease of use for recipients due to its off-the-ear configuration, smaller footprint on the head and ear, as well as its simplistic design and wireless compatibility, however; retention and patient reported hearing performance must remain acceptable.

The investigation is intended to provide the Sponsor with regional clinical experience in fitting this product on existing cochlear implant recipients prior to commercial release. The current study will evaluate the usability of the CP950 device using the CP950 Take Home Questionnaire distributed to each subject after approximately 4 weeks of take home use with the CP950 Sound Processor. Additional information such as subject datalogging and wireless pairing will also be captured. Each subject will be required to return the CP950 Sound Processor upon trial completion.

4. Study Objective

4.1 Primary Objective:

To evaluate usability of the CP950 sound processor using the CP950 Take Home Questionnaire for existing cochlear implant users. Specifically:

1) Patient Reported Hearing Performance
2) Retention & Comfort
3) Ease of use
4) Use of remote controls
5) Look & feel
6) Reliability
7) Maintenance & use

5. Study Design

The design is a within-subject usability study.

6. Study Length

The approximate length of the study for each subject is 1 month post CP950 sound processor fitting.

7. Device Description

The cochlear implant system that will be used in this study comprises:

- CP950 Sound processor
- CP950 Programming Cable Adaptor
- Cochlear Wireless Programming Pod.

7.1 Sound Processor Description

The CP950 Sound Processor is functionally comparable to the CP920 Sound Processor. Sharing the same ASIC chipset, the CP950 Sound Processor introduces a new form factor which integrates the processing unit, coil, coil cable and magnet into a single unit. As a result the CP950 Sound Processor will be worn in an OTE configuration positioned directly over the magnet of the cochlear implant on the recipients head rather than behind the ear.

7.2 Programming Software Description

Custom Sound version 4 will be used in this study.

8. Subject Population

8.1 Inclusion Criteria

- At least 6 months experience with a Nucleus 24 series or later implant in at least one implanted ear
- At least 3 months experience with the CP810,CP920 or CP910 sound processor
- Ability to complete study related questionnaires
- Willingness to participate in and to comply with all requirements of the protocol for the duration of the trial

8.2 Exclusion Criteria

- Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedure and prosthetic device
- Additional disabilities that would prevent participation in evaluations
- Implant types not currently supported by the CP950 sound processor (i.e., N22)

8.3 Release of Medical Information

Subjects will be required to release the exchange of medical information between the Investigator(s) and the Sponsor. This requirement will be clearly identified in the Informed Consent form.

9. Investigational Procedures

9.1 Design Overview

Usability of the CP950 Sound Processor with Experienced Cochlear Implant Users will be conducted as a multi-center, prospective, single-subject usability study, evaluating the usability of the CP950 Sound Processor in existing cochlear implant recipients. A single-subject research design is appropriate since it accommodates the heterogeneity that characterizes hearing-impaired populations. Blinding procedures are not appropriate for this trial design, as it is not possible to conceal the presence, or absence, of a cochlear implant from device recipients and/or clinical investigators.

9.2 Visit Schedule & Procedures

9.2.1 Visit 1:

The following activities will occur during Visit 1:

1) Subjects will be converted from their current behind the ear sound processor (CP810 or CP900 series) to the CP950 sound processor using the recommended clinical conversation parameters. An anonymous .cdx file will be sent to the Sponsor.
2) The Sound Processor MAP conversion will be completed using the Wireless Pod and Custom Sound version 4.
3) If applicable, the subjects' wireless accessories will be paired to the CP950 Sound Processor.
4) The subject will be instructed to utilize the CP950 Sound Processor, Remote Assistant or Control and wireless accessories for a minimum of 30 days +/-1 week.
5) The subject will complete a weekly diary documenting the CP950 Sound Processor user experience.

9.2.2 Visit 2:

The following activities will occur during Visit 2:

1) Datalogging for the CP950 Sound Processor will be extracted. An Anonymous .cdx file will be sent to the Sponsor.
2) The CP950 Take Home Use Questionnaire will be completed by the subject.
3) The CP950 Sound Processor will be collected from each subject.

9.3 Summary of Data Collection Visits

	Visit 1	**Visit 2**
Subject Enrollment & Informed Consent	X	
CP950 Fitting & Programming	X	X (Datalogs)
Fit Wireless Accessories	X	
Collect Subject Weekly Diary	X	X
CP950 Take Home Questionnaire - Subject		X
Return of the CP950 Sound Processor		X

10. Adverse Events

An adverse event (AE) is any undesirable clinical or medical occurrence associated with the use of the device, procedure, or participation in the study, which does not result in serious injury or illness related to the surgical procedure or the device.

A serious adverse event (SAE) is any untoward medical occurrence that

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- requires medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- leads to fetal distress, death, or congenital abnormality or birth defect
- is a medically important event or reaction

10.1 Assessment and Reporting of Adverse Events

To monitor subject safety throughout this study, any procedure or device related adverse events will be recorded. Information on all adverse events will be maintained by event type. The investigator will complete an Adverse Event form if any adverse event is reported or observed for a subject during this study, even if the event was acknowledged as a risk factor in the Informed Consent form.

Adverse device effects refer to any undesirable clinical or medical occurrence associated with use of the device or participation in the study. Any/all adverse device effects are to be recorded via the Adverse Event form. Adverse device effects will be reported if observed, even if they were acknowledged as risk factors in the Informed Consent form.

10.2 Unanticipated Adverse Device Effects

Unanticipated adverse device effects refer to any event not identified above that represents a "serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects." [FDA 21 CFR 812.3(s)]

Investigators are to inform their respective Institutional Review Boards (IRBs) and Cochlear Americas immediately if an unanticipated adverse device effect is suspected (no more than 10 working days after the investigator learns of the effect). If the case is determined to be an unanticipated adverse device effect, the investigator will fill out an "Unanticipated Adverse Device Effect Form." Cochlear Americas will report the results of an evaluation of the unanticipated adverse device effect to all reviewing IRBs and investigators within 10 working days after first receiving notice of the event.

11. Study Completion

11.1 Completed Subjects

Once the 1 month post-fitting visit is completed, the subject will be deemed complete. Each subject will be required to return the CP950 Sound Processor to the providing clinic. Subjects will continue to receive standard clinical follow-up care at their cochlear implant facility after the study.

11.2 Discontinued Subjects

Any subject may voluntarily discontinue the study at any time without prejudice. The Investigator may discontinue a subject from the study at any time if (s)he considers that remaining in the study compromises the subject's health or the subject is not sufficiently cooperative. In either event, reason(s) for discontinuation should be recorded on a study withdrawal form, provided as part of the CRFs for the study. Possible reasons for study discontinuation include the following:

- AE necessitating discontinuation from the study
- The subject is lost to follow-up
- Voluntary decision to withdraw consent made by the subject
- Investigator decision
- Other reason

In case of a subject lost-to-follow-up, the Investigator must attempt to contact the subject (or relative/family contact) by phone, email or letter at least three times. If attempts are unsuccessful, the 'subject withdrawal' form is to be completed in the study file and reported, as appropriate, in required reports to the Sponsor and IRB.

11.3 Premature Study Termination

The Sponsor may terminate the study early in the case of major non-adherence to the protocol, or if it is anticipated that recruitment will not be met for the required number of subjects to complete the study objectives. In the event of premature study termination, the subjects who are already enrolled will be sponsored through study completion.

12. Data Analysis

12.1 Statistical Analysis

All subjects who are consented into the clinical study will constitute the intention-to-treat (ITT) population for the purposes of safety evaluation. Only subjects fit with the CP950 Sound Processor and completed per the protocol will be considered as the completed cases (CC) population and per protocol (PP).

Demographic and outcomes data will be tabulated individually along with group summary descriptive statistics.

Descriptive statistics will be summarized for the following assessments:

- CP950 Take Home Questionnaire for existing cochlear implant users
- The number of connections as well as the success or failure of those connections to both the Wireless Pod and Wireless Accessories will be captured

- Field use data such as Time on Air, Listening Environment, Program Usage, and Accessory Use

12.2 Sample Size

The proposed study is designed to collect usability data on up to 30 subjects across up to 3 participating sites. Since the study was designed with the intent to collect usability data, not for the purposes of demonstrating safety and efficacy, formal sample size and power analyses have not be completed. The study is intended to provide clinical guidance and regional experience on the fitting and use associated with CP950 Sound Processor on existing cochlear implant recipients. Based on a sample size of 30 subjects, there is an approximately 80% probability of observing one or more major usability issues for issues that occur in the population at a rate of as low as 5.4%.

Subject enrollment is estimated to take 3 months to recruit up to 30 subjects across 3 sites. The enrollment period may be extended if required.

13. Risk Benefit Statement

13.1 Benefits

It is possible but not guaranteed that advances to cochlear implant technology will improve performance or increase usability of devices for future recipients. This investigation will help to inform the future development of potentially new sound processor designs as well as develop the associated clinical guidance when fitting existing cochlear implant patients. There are no direct benefits anticipated for subjects participating in this study.

13.2 Risks

With any cochlear implant mapping, there is a very small risk of unintentional over-stimulation. Subjects may experience sounds during mapping that are uncomfortably loud. Mitigation of this risk is similar to that used during clinical cochlear implant mapping wherein the sound processor is removed from the subjects head and/or the stimulation to the sound processor is ceased in Custom Sound.

There is risk that the CP950 Sound Processor will not connect wirelessly to the Wireless Pod. If this occurs, CP950 Sound Processor programming will occur using the traditional programming cable.

14. Good Clinical Practices Statement

The study obligations for the Investigator(s) are outlined in guidelines for Good Clinical Practice (GCP), ISO14155:2011 (Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice), and the Declaration of Helsinki.

15. Access to Study Documents and Study Monitoring

Investigator(s) will provide access to study documentation including source data for the purposes of monitoring, audits, IRB review, and regulatory inspections.

16. Quality Control and Assurance

Study sites may be subject to Quality audits at any point during the study. Regulatory agencies may conduct inspections during the course of the clinical investigation and after study completion.

17. Institutional Review Board

Each site will obtain approval from its designated IRB prior to commencing any study-related activities. A copy of the IRB approval will be kept in the Investigator file(s). Any additional requirements imposed by the IRB and/or regulatory authority shall be followed. The Investigator(s) will submit the appropriate documentation if any necessary extension or renewal of the IRB approval must be obtained.

18. Informed Consent Process

Written informed consent shall be obtained from each subject after explaining the rationale for and the details, aims, and objectives of the study, the risks and benefits of the trial treatment (and alternative treatments), and the extent of the patient's involvement. The Investigator is responsible for ensuring that all patients give written informed consent prior to any study-related examination or activity. All patients shall sign and date the Informed Consent Form, and a copy of the Informed Consent Form shall be given to the patient.

The Sponsor and the Investigator(s) shall avoid improper influence on or inducement of the subject, monitor, the Investigator(s) or other parties participating in or contributing to the clinical investigation.

19. Confidentiality

A Case Report Form (CRF) will be completed for each study subject, summarizing all clinical and study data. The CRF contains confidential material. Subjects will only be referred to in the CRF by their subject numbers in order to retain subject confidentiality. Specific instructions to complete the CRF shall be provided to the clinical investigation team as appropriate.

Copies of the completed CRFs are to be provided to the Sponsor as soon as practical after completion and review. The original CRFs are to be retained by the Investigator for a period of time as determined by local regulations.

20. Protocol Deviations and Amendments

The Investigator must receive prior approval from the Sponsor, and the IRB when necessary, to deviate from the protocol except in cases of emergency to protect the rights, safety, and well-being of the subjects. Emergency protocol deviations must be documented and reported to the Sponsor and the IRB.

Study procedures will not be changed without mutual agreement between the Sponsor and the Investigator(s). Changes will be implemented in a signed protocol amendment, and for significant changes, approval will be obtained from the IRB.

21. Data Management

Data will be recorded on electronic CRFs within the electronic data capture system DataLabs™. DataLabs will produce a report of the summary data per subject. Source data for study evaluations may include paper worksheets or electronic spreadsheets. All source data will be stored in subject binders or on password-protected computers. The study monitor will compare the DataLabs CRFs with the source data.

22. Record Keeping and Retention

All source documents, CRFs, and trial documentation will be kept by the Investigator(s) for the appropriate retention period as stipulated by local regulations and ICH-GCP.

23. Study Report and Publication

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

The aggregate data resulting from this study will be the proprietary information of the Sponsor and may be made public after all data have been analyzed and the study results are available. None of the data resulting from this study will be allowed to be presented or published in any form, by the Investigator or any other person, without the prior written approval of the Sponsor. At the end of the study, a clinical study report will be written by the study Investigators or their designee and reviewed by the Sponsor.