Cochlear™

Addendum to the Physician's Package Insert and Physician's Guide

Cochlear™ Nucleus® implants

CI24RE Series - including CI422, CI24RE (CA) and CI24RE (ST)

CI500 Series - including ABI541

CI600 Series

Nexa™ (CI1000) Series

CP900 Series, CP1000, CP1110, CP1150, CP1170 and CP1175 Sound Processors:

- Acoustic component
- SmartSound® iQ
- ForwardFocus
- Profile scaling

Hear now. And always

Cochlear®

About this document

This addendum contains information, clinical study, verification, and validation results to supplement the Physician's Package Insert and Physician's Guide for the following Cochlear™ Nucleus® implants:

- Cochlear Nucleus CI24RE Series implants - including CI422, CI24RE (CA) and CI24RE (ST)
- Cochlear Nucleus CI500 Series implants - including ABI541
- Cochlear Nucleus CI600 Series implants
- Cochlear Nucleus Nexa™ (CI1000) Series implants.

Contents

Acoustic component

The CP900 Series, CP1000 and CP1110 Sound Processors are integrated sound processors for cochlear implants. This means that they can provide both electric and acoustic stimulation (EAS) to Cochlear Nucleus implant recipients.

Figure 1: CP920 Sound Processor with optional acoustic component

Figure 2: CP1000 Sound Processor with optional acoustic component. This configuration is identical for the CP1110 Sound Processor.

Indications

The optional acoustic component amplifies low frequency sound, and sends it into the ear canal. The acoustic component is intended to provide access to these low frequency sounds for Nucleus cochlear implant recipients who have sufficient residual hearing.

The acoustic component is indicated for recipients of traditional Cochlear Nucleus implants with unaided air conduction thresholds less than or equal to 85 dB HL between 125 Hz and 2000 Hz following surgery. The acoustic component should only be used when behavioural audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality.

Speech perception testing should be completed before and after fitting with the acoustic component to ensure that the recipient performs as well, if not better, with the acoustic component than without it.

Benefits

In a study, 17 out of 93 (18 %) existing Cochlear Nucleus implant recipients had measurable and functional low-frequency acoustic hearing thresholds (less than or equal to 85 dB HL) after surgery at frequencies between 250 Hz and 1000 Hz.[1]

Hearing was preserved at a level that could be aided at some frequencies in these 17 adult subjects who had a Cochlear Nucleus CI422, CI512 or CI24RE internal device. Since the evaluations were completed acutely, only sound field detection was completed as opposed to speech performance testing. The subjects tested were not everyday users of combined electric and acoustic stimulation and therefore the addition of the acoustic amplification would have required adaptation and use prior to reliably testing speech performance.

1 Evaluation of Nucleus 6, Clinical Validation Results. May 2013.

The Coil On condition provided both electric and acoustic frequency specific clinically useful information for all subjects (100%). The Coil Off condition was able to provide clinically useful acoustic information to 12 of the 17 subjects (70.6%). Five of the 17 subjects were unable to be adequately amplified with the acoustic component in order to complete the frequency specific detection task. Overall, the majority of subjects (70.6%) were able to gain some benefit during the detection task when using the acoustic component alone and all subjects saw benefit when using both electric and acoustic during the detection task.

For Cochlear Nucleus implant recipients who are able to use the acoustic component, performance is likely to vary greatly based on the degree of residual hearing. Enhancement to overall hearing will likely range from improved sound quality to potentially improved performance in speech recognition. It is also possible that recipients could experience a more 'natural' sound when using the acoustic component.

Adverse effects

The risks and possible adverse effects are the same as for a traditional hearing aid.

There is a risk of mild irritation of the ear canal by hearing aid earmoulds or the ear piece of the acoustic component.

There might be some risk of interference between the electrical hearing from the cochlear implant and the acoustic hearing from the acoustic component. If this occurs, discontinue use of the acoustic component.

SmartSound® iQ

The CP900 Series, CP1000, CP1110, CP1150, CP1170 and CP1175 Sound Processors incorporate new features, that were previously unavailable on earlier generation models. Cochlear has incorporated three algorithms collectively known as SmartSound® iQ:

1. Wind Noise Reduction (WNR)
2. Signal-to-Noise Based Noise Reduction (SNR-NR)
3. Automatic Environmental Classifier (SCAN).

The CP1110, CP1170 and CP1175 Sound Processors additionally incorporate an improvement to SCAN, which is now SCAN 2, and an improved implementation of ForwardFocus. These algorithms and the existing functionality of the CP1000 Sound Processor are collectively known as SmartSound® iQ 2.

SCAN 2 classifies sound environments in the same way as SCAN, but with improved accuracy.

ForwardFocus is a clinician-enabled feature that can be user-controlled or automated to help recipients hear better in noisy environments.

For the CP1000 Sound Processor, ForwardFocus is combined with 'Zoom' directionality when activated.

For the CP1110, CP1170 and CP1175 Sound Processors, ForwardFocus is combined with 'Beam®' adaptive directionality when activated.

This new combination has shown improved hearing performance.

Features explained and non-clinical testing

Cochlear Limited has conducted a series of bench tests as well as a clinical trial to capture the intended use and environments where the features are most beneficial to the recipients.

The effectiveness of these new features have been studied with Nucleus cochlear implant recipients. This data is summarised in this addendum. SmartSound iQ processes the signal within the sound processor before it is decoded by the implant. These features operate the same way for all users regardless of the implant type.

Clinicians should use their discretion when enabling these features for auditory brainstem implant recipients, particularly if the recipient is unable to provide feedback on sound quality.

Wind Noise Reduction Algorithm

The WNR algorithm is designed to detect and reduce wind noise for enhanced comfort in windy environments. The signal detection and classification unit of the WNR algorithm identifies the presence of wind noise by separately testing the relative independence of the signals observed at each microphone to determine if local wind turbulence is present. Once wind noise is detected, the dual-omni beamformer is switched to standard directionality, and multi-channel compression is activated to suppress any residual noise.

Cochlear performed a series of non-clinical tests in a simulated environment that provides additional evidence that WNR works as designed to improve the understanding of speech in a windy environment.

Cochlear tested the WNR algorithm in the following sound environments and representative conditions:

- In a quiet environment to ensure the WNR algorithm has no impact to speech signal.
- In a non-windy but noisy environment to ensure WNR has no impact to the speech signal.
- In a windy environment to ensure WNR reduces wind-induced noise.
- In a windy environment to ensure WNR reduces wind-induced noise more than SNR-NR alone.
- In a windy environment to ensure WNR and SNR-NR reduce wind-induced noise more than WNR alone.
- In a windy environment with wind speeds up to 8 m/s or 17.89 mph.
- In a windy environment for all available directionality modes.
- Comparison of the WNR algorithm in controlled environments.

The data shows that in simulated environments the WNR algorithm is effective in reducing wind induced noise in various listening conditions and different wind speeds.

Signal-to-Noise Ratio-Based Noise Reduction (SNR-NR) function

The SNR-NR algorithm is designed to reduce intrusive surrounding inputs to the sound processor and filter them so a recipient can maintain audibility of their focus point. The intent is that background noises may be quieted while the speech signal remains consistent. The SNR-NR algorithm estimates the signal-to-noise ratio in each channel. The noise estimate is based on long-term minimum statistics, and the Signal plus Noise (S+N) measure is based on short-term energy. Noise reduction is achieved by suppressing the content of channels with poor signal-to-noise ratios, while passing the content of channels with good signal-to-noise ratios.

Cochlear performed a series of non-clinical tests in a simulated environment that provides additional evidence of the ability of the SNR-NR algorithm to reduce background noise.

Cochlear tested the SNR-NR algorithm in the following sound environments and representative conditions:

- Real speech signals as inputs into the system.
- Real speech signals in both noise and quiet.
- In use with a telephone and the telecoil input.
- In use with the FM system using the accessory input socket.
- Capture of data with no input to show SNR-NR does not interfere with speech perception in the absence of noise.
- Comparisons of SNR-NR enabled versus SNR-NR disabled in noise.
- Use with telephones that are hearing-aid compatible.
- Use with mobile phones that are not hearing-aid compatible.

The data shows that in simulated environments the use of SNR-NR is effective in reducing the impact of noise in various listening conditions and levels of background noises.

Automatic Environmental Classifier (SCAN/SCAN 2)

The Automatic Environmental Classifier (SCAN/SCAN 2) is designed to minimise the need for manual adjustment of a recipient's listening program. SCAN/SCAN 2 continuously analyses the acoustic environment, selects the most appropriate scene from a predetermined library of scenes, and automatically selects the optimal microphone configurations (for example, directional or non-directional). SCAN/SCAN 2 is enabled and disabled by the programming audiologist but SCAN/SCAN 2 can be manually overridden to standard preset mode by the user if desired. The available SCAN/SCAN 2 environments are Quiet, Noise, Speech, Speech-in-Noise, Wind and Music.

Cochlear performed a series of non-clinical tests in a simulated environment that provides additional evidence of the ability of the SCAN/SCAN 2 algorithm to switch listening environments effectively.

The accuracy of the SCAN/SCAN 2 algorithm was verified by playing 526 pre-classified sound files to the sound processor inside a test chamber and monitoring the classification. The classifications were then compared to the pre-classified scene, and the accumulated accuracy was compared against the acceptance criteria. The data shows it is not possible for the classifier to be 100% accurate, and it is preferable for certain classifications to be made over others. For example, it is more acceptable to confuse Speech with Speech-in-Noise than it is to confuse Speech with Music. *Table 1* on page 15 provides the accuracy of the classifier.

Scene	SCAN	SCAN 2
	Classification Accuracy	Classification Accuracy
Speech	68.8%	86.0%
Speech-in-Noise	67.0%	80.4%
Noise	76.8%	78.8%
Music	70.1%	84.9%
OVERALL	71.0%	82.3%

Table 1: Comparison of the accuracy of the CP1000 Sound Processor scene classifier SCAN, and the improved CP1110, CP1170 and CP1175 Sound Processor scene classifier SCAN 2

Indications

The CP900 Series, CP1000, CP1110, CP1150, CP1170 and CP1175 Sound Processor features including the Wind Noise Reduction (WNR), Environmental Classifier (SCAN/SCAN 2), and the Signal to Noise Ratio-Based Noise Reduction (SNR-NR) algorithms are intended for use in individuals six years of age or older who are able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance and 2) report a preference for different program settings.

Clinical study, verification and validation results for SmartSound® iQ

Clinical trial description

The objective of this multi-centre, pivotal study was to evaluate the safety and effectiveness of the CP900 Series Sound Processor features. The outcomes of this study are also relevant to the CP1000 and CP1150 Sound Processor features. Subjects were upgraded to the CP900 Series Sound Processor in order to evaluate the new signal processing features, including a noise reduction algorithm (SNR-NR), wind noise reduction (WNR) algorithm, and an environmental classifier (known as SCAN) that provides automatic selection of signal processing based on the listening environment. The utility of the CP900 Series Sound Processor and its new signal processing approaches were evaluated in terms of speech recognition in quiet and in noise as well as questionnaire assessment by the subjects.

The co-primary objectives were to demonstrate that, after four weeks of CP900 Series Sound Processor use (Visit Two), the mean performance on AzBio Sentences in noise with either 1) Signal to Noise Ratio Noise Reduction (SNR-NR) and/or 2) Automatic Scene Classifier (SCAN) enabled was no worse than when the features were disabled in the unilateral (implant only) listening condition.

The secondary endpoint was to demonstrate that there was no significant decrement in performance using the Wind Noise Reduction (WNR) feature when no wind noise was present. This was demonstrated using subjects' self-reported experience in hearing in windy conditions together with performance on the AzBio Sentences in noise when tested with and without the WNR algorithm in the unilateral (implant only) listening condition.

Study demographics

Demographic characteristics	Mean ± SD N (min,max)
Mean Age	47 years ± 21.6 years N (13.2 – 81.2 years)
Male	16
Female	24
Adults	31
Children	9

Table 2: Study demographics

Study inclusion and exclusion criteria

Criteria for inclusion

- Individuals aged greater than 12 years and who previously met current age-appropriate indication for cochlear implantation.
- Unilateral cochlear implant recipients of a CI24RE, CI500 or CI422 series implant.
- A minimum of three months experience with the CP810 Sound Processor.
- Prior documentation of sentence recognition testing in noise at a difficulty of +10 dB SNR or better.
- Native speaker in the language used to assess speech perception performance.
- Willingness to participate in and to comply with all requirements of the protocol.

Criteria for exclusion

- Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitation that are inherent to the prosthetic device.
- Unwillingness or inability of the candidate to comply with all investigational requirements.
- Additional handicaps that would prevent or restrict participation in the Audiological evaluations.

Description of tests

CNC Monosyllabic Word Recognition Test

The CNC Monosyllabic Word Recognition Test is a measure of open-set word recognition consisting of 10 recorded lists of 50 monosyllabic words (consonant-nucleus-consonant) such as 'laud' and 'duck'. Two lists were administered in quiet at 60 dBA in the sound field and reported as percent correct for words.

AzBio Sentence Test

The AzBio Sentence Test is a measure that consists of 33 lists of 20 sentences (such as 'He cried when the pet goat was sent to market') that contain low contextual information. Each list includes five sentences from each of four different speakers (two male, two female).

- AzBio Sentence Test in Noise

  One list was presented from a speaker positioned in front of the listener at 60 dBA with competing noise (speech weighted noise) presented at a level to achieve a +5 dB signal-to-noise ratio from a speaker positioned at 90 degrees on the side of the implant.

- AzBio Sentence Test in Quiet

  One list of the AzBio sentences was presented from a speaker positioned in front of the listener at 60 dBA without competing noise.

The Speech, Spatial, and Qualities of Hearing Scale (SSQ)

The SSQ is a validated self-assessment tool commonly used in hearing aid and cochlear implant research. It is designed to measure self-reported auditory (dis)ability across a variety of domains, reflecting the reality of hearing in the everyday world. The comparative version was used in this study in order to compare performance with the CP900 Series Sound Processor to that of the CP810 Sound Processor. The metric contains 49 questions scored by the subject using a scale of -5 to +5, where -5 corresponds to performance much worse, 0 corresponds to no change, and +5.0 corresponds to performance much better. There are three specific hearing domains assessed:

- Speech hearing scale – hearing speech in quiet and in noise, one-on-one conversation and in groups or meetings
- Spatial hearing scale – hearing where sounds are coming from, distance, movement, and ability to segregate sounds
- Qualities of hearing scale – ease of listening, naturalness, clarity, identification of different speakers, musical pieces and instruments as well as everyday sounds.

Device Use Questionnaire (DUQ)

This questionnaire (~90 questions) was developed by Cochlear and is used to collect information regarding device usability, subjective preferences, and satisfaction with regards to device use in various listening conditions. The questions summarised in this document are those related to patient satisfaction while questions centred around descriptions of device use by the study subjects are excluded.

Clinical trial results

Automatic Scene Classifier (SCAN) (Co-Primary Endpoint)

After four weeks of CP900 Series Sound Processor use 40 subjects had data available with the SCAN algorithm enabled versus disabled in the unilateral (implant ear alone) condition.

Average performance with the SCAN algorithm enabled was significantly better at 56.4% (12.1% – 94.2%) than average performance with the SCAN algorithm disabled with a mean of 31% (0.7% – 85.4%) for the 40 subjects. Results broken out by adult and paediatric populations along with a supportive efficacy analysis follows:

	Outcome	Mean±SD (95% CI)	Test	Null/Alternative Hypothesis	P-value
Paediatric Subjects (n=9)	Automatic Environment Classifier (SCAN)	-23.1 ± 17.9 (-35.9, -10.4)	Non-inferiority	Ho: P1 – P2 ≥ 10% Ha: P1 – P2 < 10%	0.0001
			Superiority	Ho: P1 – P2 ≥ 0 Ha: P1 – P2 < 0	0.0013
Adult Subjects (n=31)	Automatic Environment Classifier (SCAN)	-26.1 ± 19.2 (-33.3, -19.0)	Non-inferiority	Ho: P1 – P2 ≥ 10% Ha: P1 – P2 < 10%	<0.0001
			Superiority	Ho: P1 – P2 ≥ 0 Ha: P1 – P2 < 0	<0.0001

Table 3: Primary Efficacy Results – SCAN

	Outcome	Status	N/Total (%)
Paediatric Subjects (n=9)	Automatic Environment Classifier (SCAN) AzBio Sentence Results in Noise	Improved (>10) Same (-10 to 10) Worsened (<-10)	6/9 (66.7%) 3/9 (33.3%) 0/9 (0%)
Adult Subjects (n=31)	Automatic Environment Classifier (SCAN) AzBio Sentence Results in Noise	Improved (>10) Same (-10 to 10) Worsened (<-10)	23/31 (74.2%) 7/31 (22.6%) 1/31 (3.2%)

Table 4: Supportive Efficacy Analysis – SCAN

Understanding Speech in Quiet

After four weeks of CP900 Series Sound Processor use 40 subjects had AzBio Sentence scores in quiet available with the SCAN algorithm enabled versus disabled in the Implant Ear Alone condition.

- Average performance in the Implant Ear Alone condition with the SCAN algorithm enabled was not significantly different than average performance with the SCAN algorithm disabled when listening in Quiet.
- Average AzBio sentence scores in quiet were 86.4% (28% – 99.3%) with the SCAN algorithm disabled and 86.4% (29.5% – 100%) with the SCAN algorithm enabled in the Implant Ear Alone condition for the 40 subjects.

AzBio Sentence testing in quiet showed that performance decreased by more than 10% in 3/40 subjects when SCAN was enabled. However, the group mean for the same test and condition showed no difference with and without SCAN.

SCAN Proportional Data

After four weeks of using the CP900 Series Sound Processor with the SCAN algorithm enabled for testing of AzBio Sentences in Noise:

- Most subjects (39/40; 97.5%) performed equal to or better when with the SCAN algorithm enabled.
- Some subjects (29/40; 75%) performed significantly better.
- A few subjects (10/40; 22.5%) demonstrated similar performance with SCAN on versus off.
- One subject (1/40; 2.5%) showed a significant decrement in performance.

The results for SCAN highlight the importance of directional microphone technology for improving performance in noise. Automatic selection of the microphone response pattern is clinically important because many recipients do not manually change programs. If a recipient reports listening issues with SCAN, the clinician can use the data logs to better understand how programs are used and make modifications based on the recipient's reports. This could include deactivation of other input processing algorithms that are included in SCAN by default.

Signal to Noise Ratio Noise Reduction Algorithm (SNR-NR) (Co-Primary Endpoint)

After four weeks of CP900 Series Sound Processor use, 40 subjects had AzBio Sentence scores in noise (+5 dB SNR) available with the SNR-NR algorithm enabled versus disabled in the implant ear alone condition.

Average performance in the unilateral condition with the SNR-NR algorithm enabled was not significantly different than average performance with the SNR-NR algorithm disabled.

SNR-NR Proportional Data

After four weeks of using the CP900 Series Sound Processor with the SNR-NR algorithm enabled:

- Most subjects (39/40; 97.5%) performed equal to or better when with SNR-NR enabled.
- One subject (1/40; 2.5%) showed a significant decrement in performance.
- Some subjects (8/40; 20%) performed significantly better.
- Most subjects (31/40; 77.5%) demonstrated similar performance with SNR-NR on versus off.

The results for SNR-NR demonstrated superiority in the adult population and non-inferiority in the paediatric population.

	Outcome	Mean±SD (95% CI)	Test	Null/Alternative Hypothesis	P-value
Paediatric Subjects (n=9)	Signal-to-Noise Ratio Noise Reduction algorithm	-3.9 ± 13.6 (-13.6, 5.9)	Non-inferiority	Ho: P1 – P2 ≥ 10% Ha: P1 – P2 < 10%	0.0052
			Superiority	Ho: P1 – P2 ≥ 0 Ha: P1 – P2 < 0	0.1961
Adult Subjects (n=31)	Signal-to-Noise Ratio Noise Reduction algorithm	-5.7 ± 8.8 (-9.0, -2.4)	Non-inferiority	Ho: P1 – P2 ≥ 10% Ha: P1 – P2 < 10%	<0.0001
			Superiority	Ho: P1 – P2 ≥ 0 Ha: P1 – P2 < 0	0.0007

Table 5: Primary Efficacy Results – SNR-NR

	Outcome	Status	N/Total (%)
Paediatric Subjects (n=9)	Signal-to-Noise Ratio Noise Reduction algorithm AzBio Sentence Results in Noise	Improved (>10) Same (-10 to 10) Worsened (<-10)	3/9 (33.3%) 5/9 (55.6%) 1/9 (11.1%)
Adult Subjects (n=31)	Signal-to-Noise Ratio Noise Reduction algorithm AzBio Sentence Results in Noise	Improved (>10) Same (-10 to 10) Worsened (<-10)	5/31 (16.1%) 26/31 (83.9%) 0/31 (0%)

Table 6: Supportive Efficacy Analysis – SNR-NR

Wind Noise Reduction – Secondary Efficacy Objective

After four weeks of CP900 Series Sound Processor use 40 subjects (31 adults, 9 paediatrics) had AzBio Sentence scores in noise available with the WNR algorithm enabled versus disabled in the implant ear alone condition. For the whole group (N=40) the mean score was 24.2% (range 1.4% – 86.7%) with ADRO+ASC+SNR-NR and 30.6% (range 2.9% – 87.0%) with ADRO+ASC+SNR-NR+WNR. A further breakdown for adults versus paediatrics along with an efficacy analysis for the group are shown below:

	% Correct (Range)	
	Adult	Paediatric
ADRO+ASC+SNR-NR	21% (1.4% - 86.7%)	35% (11.7% - 69%)
ADRO+ASC+SNR-NR+WNR	29.8% (2.9% - 87.0%)	33.6% (15.2% - 62.2%)

Table 7: Secondary Efficacy Results - WNR

Additionally a subject's self-reported improvement in hearing in windy conditions together with no significant decrement in performance on the AzBio Sentences in noise when testing the SNR-NR +WNR versus SNR-NR with WNR disabled, is considered a success. A significant decrement in performance is defined to be a 10% or larger decrement.

Outcome	Status	N/Total (%)
Wind Noise Reduction	Improved (<10)	39/40 (97.5%)
AzBio Sentences in Noise	Worsened (>10)	1/40 (2.5%)

Table 8: Supportive Efficacy Analysis - WNR

WNR Proportional Data

When subjects were asked on the Device Use Questionnaire about comfort hearing in windy conditions:

- 15/40 (37.5%) were quite satisfied or very satisfied
- 16/40 (40%) were neutral
- 6/40 (15%) were quite dissatisfied or very dissatisfied
- 3/40 (7.5%) did not know

Six subjects reported dissatisfaction in hearing in windy conditions. As these subjects either improved or stayed the same in speech performance testing when using WNR, it is possible that other factors not measured in this study contributed to the dissatisfaction with the WNR algorithm. For this reason, it is important that subjects be counselled appropriately regarding any potential benefit associated with WNR.

Clinical trial results summary

Mean AzBio Sentence in Noise performance using the investigational algorithms are summarized below:

- ADRO+ASC: 18.9% (0% – 92%)
- ADRO+ASC+SNR-NR: 24.2% (1.4% – 86.7)
- ADRO+ASC+SNR-NR and WNR enabled: 30.6% (2.9% – 87%)
- All Features including SCAN: 56.4 % (12.1% – 94.2%)

Self-assessment – everyday listening condition

Speech Hearing Rating Scale

For this scale subjects answered questions concerning how well they heard and understood speech in various quiet and noisy situations involving one-on-one conversations and communication in small and large groups of people. The subjects were asked to compare their performance with their new CP900 Series Sound Processor versus their CP810 Sound Processor. The rating scale ranged from -5 (performance much worse), 0 (no change) and +5 (performance much better).

- After four weeks of experience with the CP900 Series Sound Processor in the Everyday listening condition, the average SSQ rating for the Speech Hearing Scale was 1.44 (-0.3 – +3.8) out of 5.
- Most subjects (36/40; 90%) reported benefit on the Speech Hearing Scale with the CP900 Series Sound Processor compared with their CP810 Sound Processor.
- A few subjects (3/40;7.5%) rated the CP900 Series Sound Processor as no different than the CP810 Sound Processor on the Speech Hearing Scale.
- One subject 1/40 (2.5%) reported a negative benefit rating on the Speech Hearing Scale.

Spatial Hearing Rating Scale

For this scale subjects answered questions concerning how well they could judge where a sound was coming from, how far away the sound was, and movement of sound (for example, whether a sound was coming toward them or away from them). The subjects were asked to compare their performance with their new CP900 Series Sound Processor versus their CP810 Sound Processor. The rating scale ranged from -5 (performance much worse), 0 (no change) and +5 (performance much better).

- After four weeks of experience using the CP900 Series Sound Processor in the Everyday Listening Condition the average SSQ rating for the Spatial Hearing Scale was 0.94 (-0.3 – +3.6) out of 5.
- Most subjects (32/40; 80%) reported benefit on the Spatial Hearing Rating Scale with the CP900 Series Sound Processor compared with their CP810 Sound Processor.
- A few subjects (5/40; 12.5%) rated the CP900 Series Sound Processor as no different than the CP810 Sound Processor on the Spatial Hearing Scale.
- Three subjects (3/40; 7.5%) reported a negative benefit rating on the Spatial Hearing Scale.

Sound Qualities Rating Scale

For this scale subjects answered questions concerning how well they could separate and sort out sounds, how well they could recognise different sounds, how clear or natural sounds were, and how much effort listening required. The subjects were asked to compare their performance with their new CP900 Series Sound Processor versus their CP810 Sound Processor. The rating scale ranged from -5 (performance much worse), 0 (no change) and +5 (performance much better).

- After four weeks of using the CP900 Series Sound Processor the average SSQ rating for the Sound Qualities Scale was 1.36 (-0.0 – +4.1) out of 5.
- Most subjects (38/40; 95%) rated the CP900 Series Sound Processor as better than the CP810 Sound Processor.
- Two subjects (2/40; 5%) rated the CP900 Series Sound Processor as no different.
- No subject (0/40; 0%) rated it as worse.

CP900 Series Sound Processor Questionnaire (DUQ)

After four weeks of experience with the CP900 Series Sound Processor, 40 subjects completed a questionnaire regarding their use of the CP900 Series Sound Processor.

- Most subjects (31/40; 77.5%) indicated they preferred to use the SCAN program in quiet.
- Most subjects (35/40; 87.5%) indicated they used SCAN as their preferred program in noise.
- Most subjects (39/40; 97.5%) indicated that they were quite likely or very likely to recommend the CP900 Series Sound Processor.
- Most subjects (39/40; 97.5%) were satisfied with the CP900 Series Sound Processor.
- Most subjects (39/40; 97.5%) found the CP900 Series Sound Processor relatively easy to use.
- Most subjects (38/40; 95%) indicated the CP900 Series Sound Processor either met or exceeded their expectations regarding sound quality.
- Most subjects (35/40; 87.5%) indicated they preferred the CP900 Series Sound Processor to the CP810 Sound Processor.
- Some subjects (31/40; 77.5%) indicated they were neutral, quite satisfied, or very satisfied with their comfort in hearing in windy conditions.

Adverse events

There were no adverse events reported during this clinical study.

Clinical implementation of features

SmartSound iQ incorporates environmental scene classification to automatically select input sound processing technologies. This classifier is called SCAN; it classifies the recipient's acoustic environment into one of six scenes (Speech-in-Noise, Speech, Noise, Wind, Quiet, and Music). The processor uses two omnidirectional microphones and digital signal processing to combine the microphone outputs and provide different directional response patterns. These are called 'standard directionality' (slightly directional), 'Zoom' (a forward, fixed directional response), and 'Beam' (forward, adaptive directional algorithm). SCAN automatically determines the recipient's listening environment and selects the appropriate microphone directionality, thus reducing the need for multiple sound processor programs and manual program selection. SCAN activates standard microphone directionality in Quiet, Speech, and Music, Zoom in Noise and Beam in Speech-in-Noise. This automation is valuable clinically because many recipients avoid changing programs because they are unsure which program to choose. This means speech perception may be reduced in noisy situations, for example, because the recipient fails to change from standard directionality to a more directional response pattern to improve the signal-to-noise ratio (SNR). By default, existing input signal processing algorithms of adaptive dynamic range optimisation (ADRO) and automatic sensitivity control (ASC) as well as the new signal-to-noise ratio noise reduction (SNR-NR) algorithm are available in all scenes. The wind noise reduction (WNR) algorithm activates when wind is detected. The clinician can customise a SCAN program by deactivating some of the above algorithms (ADRO, SNR-NR and WNR), as well as create customised programs that use a specific microphone directionality pattern instead of SCAN.

By default, Cochlear Custom Sound® Suite creates a SCAN program as well as a non-SCAN program using standard directionality. Both programs can be modified if necessary, based on discussion with the recipient about typical, daily listening situations, especially environments that are challenging for the individual. For example, if an existing recipient does not prefer ADRO, the clinician can disable that feature in SCAN while providing automatic microphone directionality, ASC, SNR-NR and WNR.

There may be specific scenarios when the recipient would prefer a customised program that does not include SCAN. For example, if a recipient is in a 'Speech-in-Noise' environment where the speaker is always off to one side but the recipient cannot turn to face the talker, a custom program with standard directionality and SNR-NR enabled would be a good choice. Standard directionality is nearest to an omnidirectional microphone response, with minimal attenuation of signals originating from the sides and behind the listener. In total, four programs can be created; these could include a SCAN program and three customised non-SCAN programs or, as another example, two different SCAN programs and up to two more non-SCAN programs. Custom programs that use specific directionality can be configured to include the new algorithms of SNR-NR and WNR in addition to existing input signal processing.

Features counselling and recommendations

Including at least one SCAN program for new and existing recipients is recommended because this provides the best opportunity for the recipient to automatically use the most appropriate microphone directionality throughout the day, especially in difficult listening situations. It is well known that use of directional microphone technology is an effective way to improve the SNR in most listening situations. The co-primary endpoint of AzBio Sentences in noise (+ 5dB SNR) with SCAN enabled versus disabled showed average performance improved significantly with SCAN enabled. As expected, performance in quiet (AzBio Sentences) was unchanged with SCAN.

By default, SNR-NR is included in the SCAN program. Most subjects performed similarly or better with SNR-NR enabled. If a recipient reports that sound is too quiet in some listening environments with SNR-NR enabled, the clinician can include a SCAN program with SNR-NR disabled for comparison in those specific situations.

The co-primary endpoint of AzBio Sentences in noise (+ 5 dB SNR) with SNR-NR enabled versus disabled showed that average performance was not significantly different between these two conditions. However, the standard microphone directionality response was used in this testing condition where speech was from the front and the noise source was directed to the implant side. Therefore, improvement in performance with SNR-NR enabled may not have been evident due to differences in the directional response patterns between the SCAN testing and SNR-NR testing with SCAN disabled. As noted above, directional microphone technology is an effective way to improve the SNR; it provides greater SNR improvement than noise reduction algorithms alone.

It is recommended that clinicians explain microphone directionality in a general way so that recipients understand that directional microphone response patterns attenuate sounds originating from the sides and behind the listener while preserving signals originating from the front. This is beneficial for improving speech understanding in challenging listening environments, provided the recipient faces the signal of interest. Rather than physically changing programs, which recipients often do not do, SCAN automatically adjusts the microphone response for the individual based on the identified scene. The microphone response transitions are smooth rather than abrupt. If there are specific scenarios when the recipient cannot face the signal of interest (see example in *Clinical implementation of features* on page 44), specific non-SCAN programs may be provided.

It is recommended that clinicians provide at least one program that does not include SCAN. Discussion with the recipient about specific listening situations can assist in determining the directional response pattern used. Other input signal processing features such as ASC, ADRO, Whisper™, SNR-NR, and WNR may be explored to determine an individual's preferred use of these signal processing features in various listening situations.

As part of routine follow-up, it is recommended that clinicians use the data logging feature of the sound processor to gain information for the individual related to the amount of time spent in different sound environments (scenes), average program usage, changes in other settings such as volume and sensitivity. This information can guide a discussion with the recipient about current program settings and any modifications that may improve use of the system. This is an opportunity for the recipient to discuss their experiences with each program as well as for the clinician to make programming modifications or provide additional counselling based on the information provided.

Paediatric recipient recommendations

Because the Wind Noise Reduction algorithm activates only when turbulence is detected at the microphones and because clinical study results confirm no decrement in performance when WNR is on, it is recommended that clinicians provide this feature as a default for all recipients who are ages six years and older and who are able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance and 2) report a preference for different program settings. WNR may be deactivated if there is a specific reason, including patient preference, to do so.

It is recommended that SNR-NR be made available to any recipient aged six years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings.

Results of this clinical study showed that performance improved for all recipients when listening to speech in noise and that there was no difference in performance when listening in quiet with SCAN activated. In addition to the objective performance improvement, all paediatric subjects in this clinical study indicated a subjective preference for the use of a program with SCAN activated when listening to speech in noise. It is recommended that clinicians provide at least one program with SCAN for all recipients aged six years old and older, to be used at the discretion of the recipient/parent/caregiver. In addition, it is recommended that clinicians provide at least one program that does not include SCAN as an alternative program for specific listening situations to be discussed with the care providers.

ForwardFocus

The CP1000, CP1110, CP1150, CP1170 and CP1175 Sound Processors incorporate a noise reduction feature known as ForwardFocus. ForwardFocus is a clinician-enabled feature that can be user-controlled or automated. It is designed to help recipients hear face-to-face conversations better in challenging listening environments by reducing distracting sounds occurring from behind them.

User-controlled ForwardFocus can be activated by the user through the Nucleus® Smart App and is recommended for use when listening to speech in noise. If ForwardFocus is no longer required, it may be turned off. ForwardFocus is turned off when the sound processor is turned off.

For the CP1110, CP1170 and CP1175, automated ForwardFocus is enabled in the SCAN 2 FF program. Recipients can select and deselect SCAN 2 FF as with all programs using the sound processor button or with the Nucleus Smart App. SCAN 2 FF program setting is unchanged when the sound processor is turned off. In this case, ForwardFocus is combined with the microphone directionality used by SCAN and applied in different strengths, depending on the specific scene.

<table>
<tr><th>Sound class</th><th>SCAN 2</th><th>ForwardFocus (user-controlled)</th><th>SCAN 2 FF (automated)</th></tr>
<tr><td>Quiet, Speech, Music</td><td>Standard</td><td rowspan="3">Adaptive (Beam): maximum ForwardFocus noise reduction</td><td>Standard: minimum ForwardFocus noise reduction</td></tr>
<tr><td>Noise</td><td>Fixed (Zoom)</td><td>Fixed (Zoom): maximum ForwardFocus noise reduction</td></tr>
<tr><td>Speech-in-Noise</td><td>Adaptive (Beam)</td><td>Adaptive (Beam): maximum ForwardFocus noise reduction</td></tr>
</table>

Table 9: ForwardFocus implementation

The effectiveness of the feature has been studied with Nucleus cochlear implant recipients. The data is summarised in this addendum.

Indications

ForwardFocus should only be enabled for users 12 years and older who are able to reliably provide feedback on sound quality and understand how to use the feature when moving to different or changing environments. It may be possible to have decreased speech understanding when using ForwardFocus in a quiet environment.

Clinical study, verification and validation results for ForwardFocus in CP1000

Clinical trial description

The aim of this multi-centre study was to determine whether the ForwardFocus setting provides non-inferior speech recognition performance for CP1000 Sound Processor users compared with the default SmartSound iQ setting (that is, SCAN + ADRO + ASC + SNR-NR + WNR) in a variety of test conditions. The test conditions varied in the position of the noise stimuli relative to the speech signal (that is, spatially separated or co-located from the front) and type of noise (Four-talker Babble (4TB), speech weighted noise (SWN), or none). The strength of ForwardFocus (Strong, Medium, and Mild) was also varied depending on the test condition but the comparator setting was always the SmartSound iQ default setting.

More specifically, the primary aim of the study was to determine whether ForwardFocus 'Strong', which is the setting available to the CP1000 and CP1150 Sound Processors users, provided non-inferior performance on tests of sentence recognition in 4TB noise compared with SmartSound iQ when speech and noise were spatially separated. Confirming non-inferiority between speech recognition with ForwardFocus and SmartSound iQ in the remaining test conditions were secondary aims of the study.

The aims were tested in two separate sub-studies, each sub-study included a different population: 'Conventional CI' and 'Hybrid' sound processor users. 'Conventional CI' subjects used electric only stimulation and 'Hybrid' subjects used combined electric and acoustic stimulation in the same ear (ACO attached).

Study demographics

Demographic characteristics	Conventional CI	Hybrid
	Mean ± SD N (min,max)	Mean ± SD N (min,max)
Mean Age	64.8 ± 15.6 years N (15 – 86 years)	69.7 ± 7.9 years N (53 – 82)
Male	11	11
Female	14	12
Adults	24	23
Children	1	0

Table 10: Study demographics

Study inclusion and exclusion criteria

Criteria for inclusion

- Conventional CI subject aged twelve years of age or older, or Hybrid Hearing subject aged 18 years or older.
- Cochlear implant recipients of a CI500 Series (CI512 or CI522) or CI24RE Series (CI24REH or CI422) cochlear implant.
- A minimum of three months CI experience in ear to be assessed.
- A minimum of three months experience with the CP810, CP910 or CP920 Sound Processor.
- Fluent speaker in the local language used to assess clinical performance.
- Open-set speech perception ability.
- Use of or eligibility for Hybrid Hearing acoustic component (Hybrid Hearing population only).

Criteria for exclusion

- Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations that are inherent to the investigational device.
- Unwillingness or inability of the candidate to comply with all investigational requirements.
- Additional handicaps that would prevent or restrict participation in the audiological evaluations or that would affect the scientific integrity of the study.

Study overview

A research version of Custom Sound was used to program a test CP910 or CP920 Sound Processor with the test programs for the ForwardFocus algorithm, each of the different strengths programmed into a separate program slot. ForwardFocus was implemented as a custom program coupled to Zoom SmartSound technology. Depending on the test condition, the strength of ForwardFocus was changed by the investigator via a CR230 Remote Assistant. The strength limits the amount of noise reduction provided by the algorithm: strong = 14 dB, medium = 9 dB, and mild = 4 dB of maximum attenuation. All participants were given a Nucleus 6 default program if they did not currently have one. Objective assessment of speech recognition performance using the ForwardFocus program was acutely tested during 2 to 3 study visits. No take-home experience with the ForwardFocus program was provided.

Seven different test conditions were evaluated:

Test condition	Speaker set-up	Noise type	ForwardFocus setting
1	S0N3	4TB	Strong
2	S0N3	4TB	Medium
3	S0N3	4TB	Mild
4	S0N3	SWN	Strong
5	S0N0	SWN	Strong
6	S0N0	4TB	Strong
7	S0	None (Quiet)	Strong

Table 11: Test conditions

Key: 4TB: four-talker babble, SWN: Speech weighted noise, S0N3: 3 Noise speakers @ +90, -90, & 180, speech @ 0 azimuth; S0N0: Noise and speech @ 0 azimuth.

To assess speech recognition performance in competing background noise, an adaptive speech in noise test (Dawson et al. 2013[1]) was used to determine the Speech Reception Threshold (SRT) (that is, the SNR at which the subject scored 50% words correct). Speech recognition was assessed in quiet with CNC monosyllabic words.

1 Dawson, P. W., Hersbach, A. A., & Swanson, B. A. (2013). An adaptive Australian Sentence Test in Noise (AuSTIN). Ear and Hearing, 34(5), 592–600

Description of tests

Speech Reception Threshold Test

The Speech Reception Threshold Test (SRT), included a practice list of 16 sentences (from the adaptive Australian Sentence Test in Noise (AuSTIN) sentences) presented to each subject using the first of the conditions to be tested. In the predefined counterbalanced order, two lists of 20 sentences are presented to each subject for each signal processing configuration. Subjects are asked to repeat back all the words that they hear in each sentence, and the clinician manually scores the number of morphemes correct in each sentence via the test software. If more than 50% of the morphemes in the sentence were repeated correctly, the noise increased, otherwise the noise decreased. The noise level was adjusted by 4 dB for the first four presentations and by 2 dB thereafter. The SRT was calculated from the mean SNR of the final 16 sentences, thus excluding the first four sentences. For statistical analysis, an average of the two runs was calculated.

CNC Monosyllabic Word Recognition Test

The CNC Monosyllabic Word Recognition Test is a measure of open-set word recognition consisting of 10 recorded lists of 50 monosyllabic words (consonant-nucleus-consonant) such as ‘laud’ and ‘duck’. Two lists were administered in quiet at 60 dBA in the sound field and reported as percent correct for words.

Clinical trial results

Conventional CI group

The group mean SRTs obtained in 4TB using the ForwardFocus 'Strong' (Condition1), ForwardFocus 'Medium' (Condition 2) and ForwardFocus 'Mild' (Condition 3) programs were found to be non-inferior to the group mean score measured using the Nucleus 6 default algorithm in spatially separated noise (S0N3).

The group mean SRT obtained in SWN using ForwardFocus 'Strong' was found to be non-inferior to those with Nucleus 6 defaults in both spatially separate noise (Condition 4) and co-located noise (Condition 5) conditions.

The mean SRT obtained in 4TB with ForwardFocus 'Strong' was found to be non-inferior to those obtained using the Nucleus 6 defaults in co-located noise (Condition 6).

The mean word recognition scores obtained in quiet using the ForwardFocus 'Strong' program (Condition 7) was found to be not non-inferior when compared to the mean score obtained using the Nucleus 6 defaults. Refer to *Table 15: CNC word mean scores and statistical tests comparing ForwardFocus with N6 SCAN* on page 43.

SRT results broken out by conditions follows:

Test Condition	No. of Pairs	T1: N6 Scan	T2: ForwardFocus	T2-T1 (95% Confidence Interval)
1. S0N3 4TB (strong)	24	-2.7 ± 5.2 (SD)	-4.2 ± 6.4 (SD)	-1.4 ± 2.2 (SD) (-2.4, -0.5)
2. S0N3 4TB (medium)	24	-2.7 ± 5.2 (SD)	-4.7 ± 5.7 (SD)	-2.0 ± 1.6 (SD) (-2.7, -1.3)
3. S0N3 4TB (mild)	24	-2.7 ± 5.2 (SD)	-3.6 ± 5.3 (SD)	-0.9 ± 1.2 (SD) (-1.4, -0.4)
4. S0N3 SWN (strong)	24	-8.5 ± 4.1 (SD)	-9.6 ± 3.7 (SD)	-1.1 ± 2.0 (SD) (-2.0, -0.3)
5. S0N0 SWN (strong)	24	-2.4 ± 2.4 (SD)	-3.1 ± 2.5 (SD)	-0.6 ± 1.6 (SD) (-1.3, 0.02)
6. S0N0 4TB (strong)	24	4.6 ± 3.3 (SD)	4.5 ± 3.1 (SD)	-0.1 ± 1.2 (SD) (-0.6, 0.4)

Table 12: SRT mean scores and statistical tests comparing ForwardFocus with Nucleus 6 SCAN

Test Condition	No. of Pairs	T1: N6 Scan	T2: ForwardFocus	T2-T1 (95% Confidence Interval)
7. Quiet	24	73.0 ± 17.7 (SD)	69.6 ± 20.3 (SD)	-3.3 ± 7.0 (SD) (-6.3, -0.4)

Table 13: CNC word mean scores and statistical tests comparing ForwardFocus with N6 SCAN

Hybrid group

The mean SRTs obtained in 4TB using the ForwardFocus 'Strong' (Condition 1) and 'Medium' (Condition 2) programs were found to be non-inferior to the score measured using the Nucleus 6 default in spatially separated noise. The mean SRT obtained using 'Mild' (Condition 3) was found to not meet the criteria to conclude it was non-inferior when compared with the Nucleus 6 default, as the 95% confidence intervals of the difference scores exceeded the non-inferiority margin of 1dB.

Due to the implementation of the sequential testing procedure to control type I error, and because non-inferiority was not shown for Condition 3 for the Hybrid population, the testing procedure was stopped and the hypothesis tests were not conducted for Conditions 4, 5, 6 and 7.

Test Condition	No. of Pairs	T1: N6 Scan	T2: ForwardFocus	T2-T1 (95% Confidence Interval)
1. S0N3 4TB (strong)	23	0 ± 3.6 (SD)	-1.0 ± 4.5 (SD)	-1.0 ± 1.9 (SD) (-1.9, -0.2)
2. S0N3 4TB (medium)	23	0 ± 3.6 (SD)	-0.2 ± 3.9 (SD)	-0.2 ± 1.9 (SD) (-1.0, 0.6)
3. S0N3 4TB (mild)	23	0 ± 3.6 (SD)	0.4 ± 3.7 (SD)	0.4 ± 1.8 (SD) (-0.4, 1.1)
4. S0N3 SWN (strong)	23	-5.0 ± 3.6 (SD)	-5.3 ± 3.5 (SD)	Not tested
5. S0N0 SWN (strong)	23	-1.9 ± 2.4 (SD)	-1.9 ± 2.9 (SD)	Not tested
6. S0N0 4TB (strong)	23	4.8 ± 3.0 (SD)	4.4 ± 3.0 (SD)	Not tested

Table 14: SRT mean scores and statistical tests comparing ForwardFocus with N6 SCAN

Test Condition	No. of Pairs	T1: N6 Scan	T2: ForwardFocus	T2-T1 (95% Confidence Interval)
7. Quiet	23	68.5 ± 18.6 (SD)	63.7 ± 18.0 (SD)	Not tested

Table 15: CNC word mean scores and statistical tests comparing ForwardFocus with N6 SCAN

Adverse events

There were no device-related serious adverse events during the clinical investigation. A total of four adverse events were recorded in this study. One of the adverse events was judged to be 'possibly related' to the study procedure and was 'mild' in severity. The remaining three adverse events, 2 of a serious nature and 1 mild, were all determined as not related to the study procedure or device.

Clinical implementation of features

In order to improve performance, signal processing strategies are designed to remove some or all of the competing noise, while maintaining speech targets with little or no modification. SNR-NR, the noise reduction algorithm introduced in the Nucleus CP900 Series of Sound Processors, relies on statistical properties of speech and noise (that is, amplitude modulation) to separate speech from noise. SNR-NR performs best in steady-state background noise. ForwardFocus performs best in noise such as competing talkers.

ForwardFocus assumes the signal of interest is in front of the listener and the competing noise is to the sides and/or behind the listener. If SNR-NR is enabled in a user's MAP, it can operate on the output signal from the ForwardFocus algorithm. The two noise reduction algorithms can complement each other well due to their different principles of operation.

When ForwardFocus is enabled in the recipient's MAP by their clinician, and the recipient has switched on ForwardFocus using the Nucleus Smart App, ForwardFocus temporarily overrides the microphone directionality of the current program except in the following scenarios:

- If Wind Noise Reduction (WNR) is enabled and wind is detected, ForwardFocus is overridden by WNR and the Low Noise microphone setting is used.
- If an accessory, telecoil or audio streaming is in use, ForwardFocus is temporarily deactivated. When the accessory, telecoil or audio streaming is disabled, ForwardFocus resumes.

Signal-to-Noise Ratio-Based Noise Reduction (SNR-NR) is independent of ForwardFocus. If SNR-NR is enabled, background noise is always automatically reduced regardless of the microphone directionality. If ForwardFocus is also enabled and is switched on using the Recipient Smart App, noise occurring behind the recipient is further reduced.

Features counselling and recommendations for CP1000 Sound Processor and CP1150 Sound Processor

For the Conventional CI sub-study, speech perception performance with ForwardFocus was shown to be no worse than that obtained with the Nucleus 6 default setting in both babble and steady state noise environments. The benefits of ForwardFocus were shown when the noise was spatially separated from the speech (S0N3) and with four-talker babble. However, the performance in quiet using ForwardFocus did not meet the criteria for non-inferiority when compared to performance obtained using the Nucleus 6 default program.

For the Hybrid sub-study, speech perception performance with ForwardFocus was shown to be no worse than that obtained with Nucleus 6 default setting for ForwardFocus 'Strong' and 'Medium' settings when the noise was spatially separated from the speech (S0N3) and with four-talker babble. Non-inferiority could not be claimed for the ForwardFocus 'Mild' setting in spatially separated four-talker babble noise due to the 'inconclusive' result in which the 95% confidence intervals extend through 0 and the non-inferiority margin of 1.

The primary aim of the study was confirmed for both sub-studies; non-inferior performance was obtained using the ForwardFocus 'Strong' setting in four-talker babble noise compared with Nucleus 6 default in spatially separated noise. For the Conventional CI sub-study, in the remaining tested noise conditions, speech recognition performance using the SpatialNR settings were at least non-inferior to those obtained using the Nucleus 6 default program.

The commercial implementation of the ForwardFocus algorithm only provides the equivalent of the 'Strong' setting to the recipient. As a result it is expected that both conventional CI and Hybrid CI recipients will benefit from ForwardFocus in noisy environments, particularly in environments with babble noise originating from behind the subject.

The ForwardFocus algorithm was designed for use in noisy situations. Clinically the ForwardFocus algorithm must first be enabled by the clinician for the cochlear implant user and secondly it must be activated by the cochlear implant user or caregiver of the cochlear implant user. In parallel to counselling for the recommended use, this sequence of activation helps to ensure the benefits of ForwardFocus are realised and applied by the cochlear implant user for specific noisy environments. It is recommended that the recipient is counselled to remember to turn off ForwardFocus when moving to a different environment, for example when moving to a quiet room. ForwardFocus is deactivated when the sound processor is turned off. This helps reduce the risk of cochlear implant users leaving the feature activated in quiet environments. Clinicians should counsel their recipients to turn it off when the recipient changes listening environments.

Before enabling ForwardFocus, clinicians should ensure that recipients can correctly identify quiet and noisy environments. Because the algorithm for ForwardFocus assumes the sound signal of interest is in front of the recipient, and the competing noise is to the side and/or behind the recipient, clinicians should counsel recipients to orient themselves so that distracting sounds are behind them, and the sound they want to hear is in front of them. Clinicians should provide the recipient with several listening scenarios such as a noisy playground, a noisy classroom, or listening in a cafe, to ensure that the patient understands how to orient themselves in front of the noise to ensure maximum benefit of the ForwardFocus feature.

Clinical study, verification and validation results for ForwardFocus in CP1110

Study of speech perception with the CP1110 Sound Processor compared with the CP1000 Sound Processor

Clinical trial description

A pivotal, prospective, pre-market, multi-site, non-randomised, open-label, within-subject, repeated-measures clinical investigation studied the performance and clinical benefits of features introduced with the CP1110 Sound Processor. The investigation was in adults with sensorineural hearing impairment who are current users of a Nucleus Cochlear implant system.

This study compared the speech performance with the CP1110 Sound Processor with the commercially available CP1000 Sound Processor, with particular focus on the new microphones and inclusion of the noise reduction feature ForwardFocus in the Automatic Scene Classifier 'SCAN'. More specifically, speech recognition data using the CP1110 Sound Processor in quiet was gathered to assess whether the increased noise floor of the new microphones has a clinical impact. Speech recognition data in quiet and noise was also gathered to assess whether the automation of ForwardFocus in SCAN provides at least the same speech recognition performance when compared with the CP1000 Sound Processor.

Study demographics

Demographic information is summarised below:

- **Age**: All subjects were aged between 33 and 91, with an average age of 65 years.
- **Gender**: 65% (13) were females and 35% (7) were males.
- **Onset of hearing loss**: The average age of onset of reported hearing loss was 21.2 years (test ear) and 21.9 years (contralateral ear). All subjects (100%) reported sensorineural hearing loss. Progressive and progressive with sudden hearing loss accounted for 75% of the reported hearing loss in the test ear, and 30% of the subjects reported hearing loss due to genetics.
- **Initial hearing aid use**: The average age at initial hearing aid use was 28.7 years for the test ear (N = 18), with a median of 28 years, and an average age of 32.9 years for the contralateral ear (N = 16), with a median of 31.5 years. The minimum and maximum values for initial hearing aid for either ear was 2 years and 61 years. When hearing aids were used, all subjects used them continuously.
- **Time since cochlear implant (CI) surgery**: The average time since cochlear implant surgery was 9.7 years for the test ear (N = 20), with a median of 10 years, and 12.6 years for the contralateral ear (N = 16), with a median of 13.4 years. The minimum and maximum time since cochlear implant surgery was 0.5 years and 16.7 years for the test ear, and 1.9 years and 20.8 years for the contralateral ear.

Study inclusion and exclusion criteria

Criteria for inclusion

- Aged 18 years or older.
- Postlingually deafened.
- Implanted with the CI600 Series implants (CI612, CI632, CI622, CI624), CI500 Series implants (CI512, CI532, CI522) or Freedom Series implants (CI24RE (CA), CI24RE (ST), CI422).
- At least 6 months experience with a cochlear implant.
- At least 3 months experience with a CP910/CP920, CP950, CP1150 or CP1000 Sound Processor.
- Able to score 30% or more at +15 SNR with CI alone on a sentence in babble test.

- Willingness to participate in and to comply with all requirements of the protocol.
- Fluent speaker in English as determined by the investigator.
- Willing and able to provide written informed consent.

Criteria for exclusion

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

Study overview

The primary objective of the study was to characterise adult cochlear implant speech perception in spatially separated speech and noise (S0N90) with the CP1110 Sound Processor with ForwardFocus ON (Beam) compared with the CP1000 Sound Processor with ForwardFocus ON (Zoom). This was characterised by the paired difference in dB SRT (AuSTIN).

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

This study had a non-inferiority design; therefore, the primary analysis was based on the PP population, with analysis based on the ITT population to provide supporting evidence for non-inferiority endpoints.

- The **Intent-to-Treat Population** included all subjects who received the treatments and had at least one set of paired treatment and control measurements from any endpoint, regardless of protocol deviations and missing data. The Intent-to-Treat analysis population provided supportive evidence to non-inferiority test and were the main analysis population for superiority tests.
- The **Per Protocol Population** included all subjects who received the treatments and had at least one paired measurement from treatment and control, without major protocol deviations. Major deviations were defined at the clean file meeting before database lock.
- The **Safety Population** included all treated subjects. The Safety Population was used for the safety data analysis.

Study results

Twenty subjects were recruited in the study. No subjects were withdrawn from the study after screening, and all subjects received all performance evaluations and procedures. All subjects received their planned test sequence with subjects assigned an odd numbered subject identifier receiving the CP1000 Sound Processor followed by the CP1110 Sound Processor and those subjects with an even numbered subject identifier receiving the CP1110 Sound Processor followed by the CP1110 Sound Processor. In this study, subjects included in ITT, PP and Safety analysis populations were the same (N = 20).

Two runs were conducted on each sound processor for each speech outcome measure. The average of the two runs (per sound processor) was used as the source data for the analyses for each endpoint. In this study, each subject in the study completed both runs per sound processor for each endpoint. Consequently, there were 20 paired (one for each sound processor) observations (calculated as the mean across two runs) available for analysis.

Primary endpoint

The primary effectiveness endpoint is the Speech Recognition Threshold (SRT) score (dB) in noise (S0NCI, 4TB) compared between CP1110 ForwardFocus ON (Beam) and CP1000 ForwardFocus ON (Zoom).

There were 20 paired data from PP population included for the analysis, with no missing data in the analysis. The SRT in noise score decreased with CP1110 ForwardFocus ON (Beam) compared with CP1000 ForwardFocus ON (Zoom), with a decrease in SRT of -5.23 dB (95% CI: -6.16, -4.29). As the upper limit of the 95% confidence interval was below the non-inferiority margin of 1 dB, the CP1110 ForwardFocus ON was considered non-inferior to the CP1000 ForwardFocus ON.

Given that non-inferiority was demonstrated, the testing proceeded to a test of superiority. As the p-value ($p < 0.001$) associated with this test of superiority was less than the significance level of 0.05, and the difference favoured (lower is better) CP1110 ForwardFocus ON (Beam), superiority was demonstrated compared with CP1000 ForwardFocus ON (Zoom).

Secondary endpoints

The results of the secondary endpoints are summarised in *Table 16*. For each endpoint, there were 20 paired data in the PP population, with no missing data in the analysis. The difference in results between the CP1110 and CP1000 Sound Processors was taken for each endpoint, and non-inferiority was determined with a 95% confidence interval (CI). Superiority testing was also completed with a pre-specified significance level of 0.05.

End-point	Data	Difference	Non-inferiority margin	Superiority test (p-value)	Result
1	CNC Words in Quiet (SNR-NR ON)	0.6% (95% CI: -2.24%, 3.44%)	-10%	p=0.663	Non-inferior, not significantly superior
2	CNC Words in Quiet SNR-NR OFF (Expander ON for CP1110)	3.75% (95% CI: -6.91%, -0.59%)	-10%	p= 0.022	Non-inferior, significantly worse[1]
3	CNC Words in Quiet score of CP1110 ForwardFocus ON (moderate) vs CP1000 SNR-NR ON	1.15% (95% CI: - 3.94%, 1.64%)	-10%	p=0.400	Non-inferior, not significantly superior
4	SRT (dB) in Noise (S0N0 4TB): CP1110 ForwardFocus ON (Beam) vs CP1000 ForwardFocus ON (Zoom)	0.18 dB (95% CI: -0.43, 0.79)	1 dB	P=0.546	Non-inferior, not significantly superior

Table 16: Summary of secondary endpoints - speech perception with the CP1110 Sound Processor compared with the CP1000 Sound Processor

Adverse events

There were no adverse events recorded in the study.

1 While CP1110 SNR-NR OFF (Expander ON) is significantly worse (lower) than CP1000 SNR-NR OFF, its decreased performance is within the acceptable margin for non-inferiority.

Study of acceptance and performance with experienced adult cochlear implant recipients using the CP1110 Sound Processor compared with the CP1000 Sound Processor

Clinical trial description

A pre-marketing, prospective, single-site, open-label, with in subject, pivotal, interventional clinical study investigated adult cochlear implant users' speech performance, usability and acceptance of the CP1110 Sound Processor, including use of the new program automating ForwardFocus as part of SCAN 2, known as SCAN 2 FF. The investigation was in adults with sensorineural hearing impairment who are current users of a Nucleus Cochlear implant system.

This study compared the speech performance with the CP1110 Sound Processor with the commercially available CP1000 Sound Processor, with particular focus on the new microphones and inclusion of the noise reduction feature ForwardFocus in the Automatic Scene Classifier 'SCAN'. More specifically, speech recognition data using the CP1110 Sound Processor in quiet was gathered to assess whether the increased noise floor of the new microphones has a clinical impact. Speech recognition data in quiet and noise was also gathered to assess whether the automation of ForwardFocus in SCAN provides at least the same speech recognition performance when compared with the CP1000 Sound Processor.

Study demographics

Demographic information is summarised below:

- **Age**: All subjects were aged between 28 and 91, with an average age of 61 years
- **Gender**: 55% (11) were females and 45% (9) were males.
- **Onset of hearing loss**: The average age of onset of reported hearing loss was 21.4 years (test ear) and 20.8 years (contralateral ear). Most subjects (95%) reported sensorineural hearing loss in the test ear. Progressive and progressive with sudden hearing loss accounted for 75% of the reported hearing loss in the test ear, and 35% of the subjects reported hearing loss due to genetics.
- **Initial hearing aid use**: The average age at initial hearing aid use was 26.0 years for the test ear, with a median of 18.5 years (N=18), and an average age of 25.9 years for the contralateral ear, with a median of 17 years (N=17). The minimum and maximum values for initial hearing aid 3 and 61 years for the test ear and 1.5 and 61 years for the contralateral ear. At time of enrollment into the study, two subjects (11.8%) had continued use of a hearing aid in the contralateral ear.
- **Time since CI surgery**: The average time since cochlear implant surgery was 10.8 years for the test ear (N = 20), with a median of 10.9 years, and 11.7 years for the contralateral ear (N = 16), with a median of 12.3 years. The minimum and maximum time since cochlear implant surgery was 3 years and 20.8 years for the test ear, and 1.9 years and 19.9 years for the contralateral ear.

Study inclusion and exclusion criteria

Criteria for inclusion

- Aged 18 years or older.
- Postlingually deafened.
- Implanted with the CI600 Series implants (CI612, CI632, CI622, CI624), CI500 Series implants (CI512, CI532, CI522) or Freedom Series implants (CI24RE (CA), CI24RE (ST), CI422).
- At least 6 months experience with a cochlear implant.
- At least 3 months experience with a CP1000 Sound Processor.
- Able to score 30% or more at +15 SNR with CI alone on a sentence in babble test.
- Willingness to participate in and to comply with all requirements of the protocol.
- Fluent speaker in English as determined by the investigator.
- Willing and able to provide written informed consent.

Criteria for exclusion

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

Study overview

The primary objective of the study was evaluate adult cochlear implant speech perception in spatially separated speech and noise (S0Nrearhalf) with the CP1110 Sound Processor with ForwardFocus ON (SCAN) compared with ForwardFocus OFF (SCAN). This was characterised by the paired difference in dB SRT (AuSTIN).

Like the study of speech perception with the CP1110 Sound Processor compared with the CP1000 Sound Processor summarised above, the analysis of the primary endpoint was based on the Intent-To-Treat (ITT) and Per Protocol (PP) analysis populations to support a conclusion of non-inferiority. The inclusion of both ITT and PP populations was chosen to assess the robustness of the study results and the consistency of the study measures under different analysis populations.

This study had a non-inferiority design; therefore, the primary analysis was based on the PP population, with analysis based on the ITT population to provide supporting evidence for non-inferiority endpoints. For a definition of the ITT, PP, and Safety populations, refer to ***Study of speech perception with the CP1110 Sound Processor compared with the CP1000 Sound Processor*** on page 47.

Study results

Except for the patient reported outcomes, which are described further on page 58, the results of the endpoints are summarised in ***Table 17*** on page 57 with the primary endpoint appearing first. For each endpoint, there were 20 paired data in the PP population, with no missing data in the analysis. The difference in results between the CP1110 and CP1000 Sound Processors was taken for each endpoint, and non-inferiority was determined with a 95% confidence interval (CI). Superiority testing was also completed with a pre-specified significance level of 0.05.

The third secondary endpoint utilises the SSQ12, which is Speech, Spatial and Qualities of Hearing. The SSQ12 contains 12 questions and is a reduced version of the full 49 question SSQ questionnaire. Responses are marked on a scale of 0-10, with higher scores meaning better performance of the sound processor.

End-point	Data	Difference	Non-inferiority margin	Superiority test (p-value)	Result
Primary	SRT score (dB) in Noise (S0Nrearhalf) between CP1110 with ForwardFocus ON (SCAN 2 FF) and CP1110 with Forward Focus OFF (SCAN 2)	-4.3 dB (95% CI: -5.2 dB to -3.4 dB)	1 dB	p<0.001	Non-inferior, SCAN 2 FF is significantly superior to SCAN 2 in CP1110 Sound Processor
1	SRT score (dB) in 3-speaker configuration (S0N3) between CP1110 with ForwardFocus ON (SCAN 2 FF) and CP1110 with Forward Focus OFF (SCAN 2)	-4.2 dB (95% CI: -4.6 to -3.5)	1 dB	p<0.001	Non-inferior, SCAN 2 FF is significantly superior to SCAN 2 in CP1110 Sound Processor
2	CNC Words in Quiet (% correct) between CP1110 and CP1000 (S0, 50 dB SPL)	3.6% (95% CI: 0.8 to 6.4)	-10%	p=0.016	Non-inferior, CNC Words in Quiet with CP1110 is significantly superior to CNC Words in Quiet with CP1000
3	SSQ12 scale at baseline (CP1000) versus at visit 2 (CP1110)	0.01 (95% CI: -0.58, 0.61)	-1	p=0.964	Non-inferior, the difference in SSQ12 scores is not significantly different

Table 17: Summary of endpoints - acceptance and performance of experienced cochlear implant users with CP1110 Sound Processor

Patient reported outcomes were collected via questionnaires. The ease of use and user experience with the CP1110 Sound Processor, associated components and the automation of ForwardFocus in SCAN 2 (SCAN 2 FF) in environments of actual use were analysed descriptively. Subjective outcomes indicated consistent use of the CP1110 Sound Processor, and general group acceptance and satisfaction.

Adverse events

Twenty-two (22) adverse events (AEs) were recorded in this study at the database lock:

- Four subjects (20.0%) reported five ear-related AEs, which included four events of mild severity and one of moderate severity.
  - Mild severity events: loud stimulation related to TV and/or phone, streaming (n=2), ear soreness due to the strength of the magnet (n=1), and headache due to the strength of the magnet (n=1).
  - Moderate severity event: single-sided Meniere's attack (n=1) and was not considered to be related to the device or the investigational procedure. The action taken to resolve this issue was a period of non-use.
- Nine (45.0%) subjects reported 17 AEs that were not related to the ear, which included 14 events of mild severity and 3 events of moderate severity experienced by one subject, all of which were unrelated to the device or investigational procedure, and the treatment did not impact the study.

All events were resolved or resolving at the time of study completion.

Device deficiencies

All 20 (100%) subjects recorded at least one device deficiency (DD), with 156 DD events recorded. Of these, 90 deficiencies were related to the sound processor performance. Connectivity was the second most reported issue with 13 subjects (65.0%) reporting 32 deficiencies. The remaining 34 DD events were spread between durability (40%), reliability (30%), safety (30%), 'other' (20%) and quality (10%).

Two subjects (10.0%) experienced a DD event that led to an AE. Both these were reported as AEs relating to loud stimulation during streaming. Both were considered minor in severity. Neither DD led to a serious adverse event (SAE).

Features counselling and recommendations for CP1110, CP1170 and CP1175 Sound Processors

User-controlled ForwardFocus for the CP1110, CP1170 and CP1175 Sound Processors is designed for use in face-to-face conversations in noisy situations. It is not designed for use in quiet environments. Clinicians should counsel recipients to turn off ForwardFocus when the recipient changes listening environments.

For the CP1110, CP1170 and CP1175 Sound Processors, ForwardFocus can also be offered as an automated program, known as SCAN 2 FF. In this program, the ForwardFocus noise reduction is implemented according to the scene classification.

For noise, and speech in noise situations, the SCAN 2 FF program provides maximum noise attenuation to ensure the benefits of ForwardFocus are realised.

In quiet, speech, and music situations, the SCAN 2 FF program provides a minimum level of attenuation. A clinical study has shown that there are no negative effects to speech understanding, and therefore the SCAN 2 FF program does not need to be turned off in quiet, speech, and music situations.

Paediatric recipient recommendations

ForwardFocus should only be enabled for users 12 years and older who are able to reliably provide feedback on sound quality and understand how to use the feature when moving to different or changing environments. It may be possible to have decreased speech understanding when using ForwardFocus in a quiet environment.

Profile scaling

It has been observed that when T and C levels are measured at each electrode of a MAP created using psychophysical measurements of T and C levels, a flattening effect of the C levels compared to T levels has been observed due to spread of excitation. Such differences in the shape of T and C level profiles may be lost when the MAP profile is created based on measurements from a fewer number of electrodes.

To help mimic the natural flattening, Cochlear created an embedded algorithm known as profile scaling that is automatically applied in Custom Sound Pro. Profile scaling subtly shapes the T and C level profiles to help mimic some of the observed natural flattening of C and T level profiles. MAPs with profile scaling applied have been shown to be preferred by recipients compared to MAPs without profile scaling applied. (Botros & Pssaros, 2010)

The profile scaling algorithm is non inferior to instances where profile scaling is not applied. This conclusion is supported by clinical data from three different sources:

1. Retrospective Intrasubject Study of Real-World Fitting Data to Assess the Efficacy of NRT Profile Scaling in Predicting Behavioral MAPs
2. Effectiveness and Safety of Profile Scaling In Pediatric Cochlear Implant (CI) Recipients
3. Assessment of the impact of profile scaling on speech outcomes in adults – Clinical Report

Retrospective Intrasubject Study of Real-world Fitting Data to Assess the Efficacy of NRT Profile Scaling in Predicting Behavioral MAPs

This study used retrospectively collected real world data comprising of 2,526 subjects over a range of age cohorts (12 months to 80 years old) to investigate the non-inferiority of NRT profile scaling in comparison to NRT profile shifting at accounting for T levels and C levels that are established psychophysically.

The primary objectives of the study were to:

- Assess the non-inferiority of NRT profile scaling in matching psychophysically attained T levels with NRT profile shifting being the control.
- Assess the non-inferiority of NRT profile scaling in matching psychophysically attained C levels with NRT profile shifting being the control.

The margin of non-inferiority was determined to be 3 current levels (CL). For each subject's program and corresponding NRT Thresholds, the difference between (Root Mean Square Errors) RMSEs were calculated to compare scaled versus shifted profiles for both T levels and C levels. The RMSE measurement is a measure of how well the shifted NRT thresholds or profile scaled NRT thresholds account for the T levels or C levels. If the RMSE equals zero, the shifted or scaled profiles match for the T levels or C levels. The difference between the RMSE of the shifted NRT and the RMSE of the scaled NRT informs whether NRT profile scaling has better accounted for the psychophysically established program:

Additional exploratory objectives of the study were:

- On an individual electrode level (or channel), describe the ability of NRT profile scaling in matching psychophysically attained T levels in comparison to NRT Profile Shifting.
- On an individual electrode level (or channel), describe the ability of NRT profile scaling in matching psychophysically attained C levels in comparison to NRT Profile Shifting.

For each electrode, the absolute differences were calculated between the shifted/scaled profile and the T levels as well as between the shifted/scaled profile and the C levels. Then, the difference between the absolute differences of shifted NRT profile and scaled NRT profile was calculated.

To be included in the data analysis subjects met the following criteria:

- Subjects of any age
- Subjects with Nucleus CI512, CI522 and CI532 implants fitted with default program settings:
  - MAP programmed in streamline mode
  - Pulse width of 25µs
  - Stimulation rate of 900Hz
  - Maxima of 8
  - MAP strategy ACE
- Subjects with NRT measurements made using the AutoNRT algorithm.

Results

The following tables summarise the subject demographics and baseline characteristics. There was a total of 2,526 subjects included in the data analyses.

Cohort	Age cohort		Subjects
	Lower	Upper	
All	N/A	N/A	2,526
0-2	0	2	207
2-4	2	4	611
4-8	4	8	584
8-12	8	12	205
12-18	12	18	103
Adults	18	89	816

Table 18: Subject demographics

Cohort	Ages (years)				
	Min	Max	Median	Mean	SD
All	1	80	6	23.40	28.19
0-2	1	2	2	1.59	0.27
2-4	2	4	3	2.91	0.56
4-8	4	8	5	5.54	1.09
8-12	8	12	10	9.77	1.19
12-18	12	18	14	14.48	1.78
Adults	18	80	68	61.62	16.66

Table 19: Baseline characteristics

Cohort	Implants (%)		
	CI512	CI522	CI532
All	73.99	3.88	22.13
0-2	71.50	2.90	25.60
2-4	77.41	2.13	20.46
4-8	82.88	2.23	14.90
8-12	87.80	4.39	7.80
12-18	75.73	5.83	18.45
Adults	62.01	6.25	31.74

Table 20: Demographic implant information

T and C level differences

NRT profile scaling was found to be non-inferior to NRT Profile Shifting for all subject cohorts for both T and C levels. The results for the T levels are summarised in *Table 21* and for C levels in *Table 22*. Furthermore, it was found that for all subject age cohorts and all electrodes, the difference between the absolute error in accounting for T levels and C levels is negative. This suggests that NRT profile scaling better predicts or matches T levels than NRT shifting.

Cohort	Crit. t-stat.	Mean (CL[1])	Standard deviation (CL)	Standard error (CL)	Upper Bound Conf. Int. (CL)	Non-inferiority (CI_u<3 CL)
All	2.58	-1.44	1.68	0.03	-1.35	True
0-2	2.60	-1.96	1.94	0.14	-1.61	True
2-4	2.58	-1.63	1.63	0.07	-1.46	True
4-8	2.58	-1.47	2.08	0.09	-1.24	True
8-12	2.60	-1.21	1.35	0.09	-0.97	True
12-18	2.62	-1.49	1.47	0.14	-1.11	True
Adults	2.58	-1.19	1.36	0.05	-1.07	True

Table 21: T Level difference

1 CL = current levels

Cohort	Crit. t-stat.	Mean (CL[1])	Standard deviation (CL)	Standard error (CL)	Upper Bound Conf. Int. (CL)	Non-inferiority (CI_U<3 CL)
All	2.58	-2.76	3.34	0.07	-2.59	True
0-2	2.60	-3.54	3.74	0.26	-2.87	True
2-4	2.58	-2.87	3.27	0.13	-2.53	True
4-8	2.58	-2.56	4.05	0.17	-2.12	True
8-12	2.60	-2.39	2.79	0.19	-1.88	True
12-18	2.62	-3.12	2.91	0.29	-2.37	True
Adults	2.58	-2.67	2.84	0.10	-2.41	True

Table 22: C level difference

Study conclusion

This study supports that NRT profile scaling is non-inferior to NRT Profile shifting for all age cohorts. When executing the primary hypothesis of this study, it was found that NRT profile scaling was non-inferior for all subject cohorts. There is also strong evidence that NRT profile scaling is superior to NRT profile shifting, as the upper bounds of the 99% confidence intervals are less than zero. By observational inference, the exploratory analysis found that for all subject age cohorts and for all electrodes, the majority of the difference in absolute error distributions were less than 3CL the margin of non-inferiority.

1 CL = current levels

Effectiveness and Safety of Profile Scaling in Pediatric Cochlear Implant (CI) Recipients

This retrospective non-interventional study used real-world data to evaluate the effectiveness and safety of MAPs created using profile scaling in a group of young paediatric cochlear recipients.

Subjects were divided into two groups:

- Treatment Group: subjects who had been programmed with profile scaling applied to the MAP.
- Control group: subjects who had been programmed without profile scaling being applied to the MAP. This group served as a baseline for comparability for potential differences in response to the programming algorithm.

Results

Subjects were between the ages of 9-12 months of age at time of cochlear implantation and were implanted with either the Nucleus CI24RE, CI500 or CI600 implants. The demographics and baseline characteristics of the 133 subjects that were evaluated are provided in *Table 23*. (Values reported are mean (standard deviation), median (min, max) or n/total (%) as appropriate.)

Variable		Without profile scaling N=101	With profile scaling N=32
Age (months)	N Mean ± SD Median (Min, Max)	101 10.06 ± 0.870 10.00 (9.0, 11.0)	32 9.88 ± 0.871 10.00 (9.0, 11.0)
Gender	N	101	32
	Male	55.4% (56/101)	46.9% (15/32)
	Female	44.6% (45/101)	53.1% (17/32)
Audiometric Thresholds in the implanted ear (PTA-500, 1000 & 2000 Hz)	N[1] Mean ± SD Median	154 100.3 ± 9.487 100.8 (75.0,115.0)	48 102.7 ± 12.150 105.0 (55.0,116.7)

Table 23: Subject demographics and baseline characteristics

Primary effectiveness endpoint

Using the clinically accepted practice of test re-test reliability within 10 dB, mean average aided audiometric threshold data between the two groups was compared. As shown in ***Table 24*** results demonstrate that MAPs with profile scaling applied (28.7 dB) are non-inferior to MAPs where profile scaling (29.4 dB) was not applied. The mean difference between groups was 0.68 dB HL (p<.0001). These outcomes support the hypothesis that the profile scaling algorithm when enabled does not appear to compromise auditory detection.

1 This N represents implanted ears. All other Ns represent subjects.

Post-operative		Difference[1]	
Without profile Scaling N[2] Mean ±SD[3], Median (min, max)	With profile Scaling N Mean ±SD, Median (min, max)	Mean (95% CI[4])	P-value[5]
157 29.4 ± 8.34 28.0 (16, 85)	49 28.7 ± 6.76 29.0 (15, 60)	0.68 (-1.90, 3.26)	<.0001

Table 24: Soundfield aided audiometric thresholds (dB HL) in the treated ear at 24-months postactivation

Secondary effectiveness endpoint

Comparable outcomes were observed in both groups using the LittlEARS and IT-MAIS questionnaires with mean change scores of 52.9% and 59.8% in the profile scaling group and 63.6% and 53.5% for the group without profile scaling applied respectively.

Safety outcomes

Only two safety events were identified as associated with device programming across all subjects. (1. Crying due to loudness discomfort and 2. Crying and eye blinking due to loudness discomfort with temporary non-use). Both events were reported as non-severe, anticipated events related to the device and were resolved with reprogramming.

1 The mean and CI for difference, and p-value, are based on two sample t-test with a one-sided 0.05 alpha level.
2 N represents number of ears
3 SD = standard deviation
4 CI = confidence interval
5 P-value is reported from the Pooled method.

Conclusion

The results obtained for post-treatment aided auditory threshold outcomes suggest that profile scaling did not have a detrimental effect on the subject's ability to detect sounds necessary for speech development. Additionally, parental questionnaire outcomes, the precursor to the development of spoken language, further support that irrespective of profile scaling activation within the device programming, outcomes were comparable. Finally, review of safety related events within this young recipient group supports no added risks imposed by the activation of profile scaling within device programming in this population. Taken together, these results demonstrate with reasonable assurance the safety and effectiveness of the profile scaling feature when applied to a MAP in a paediatric cochlear implant (CI) population.

Impact of profile scaling on speech outcomes in adults

To further evaluate the impact of profile scaling on speech performance, data from two prospectively planned studies was available for analysis. The first, the CI532 Benchmark Study (G160256), was conducted before profile scaling was incorporated into the programming software. The second, the CI632DEX study (G200098), included profile scaling as a programming option. The CI632DEX study is a randomised, controlled prospective, multicentre multi-country study. Subjects were randomised in a 1:1 ratio to either the CI632 device (control) or the CI632D device (experimental). Only subjects in the control group were considered for this analysis. There were 13 subjects randomised into the control group of which 7 used profile scaling. There were 96 subjects in the CI532 Benchmark study. Study inclusion criteria was similar across the studies.

Results

The demographic and baseline disease characteristics of the subjects included in the CI532 Benchmark Study (without profile scaling) and the subjects randomised/implanted to the control arm (CI632) of the CI632DEX Study who had profile scaling enabled were largely similar. Aside from the difference in the exposure to profile scaling, there appear not to be any obvious sources of differences at baseline that could contribute to differences in the speech outcomes data post-baseline.

Speech outcomes

The descriptive summary of word recognition in quiet in the cochlear implant alone condition are presented in ***Table 25***. The CNC words in quiet were comparable at baseline between the cohorts. The improvements at 6 months were 46.3% (CI532 Benchmark Study) and 68.7% (profile scaled subjects in the control arm [CI632] of the CI632DEX Study) suggesting that there is no discernible detriment to speech recognition in quiet as a result of having profile scaling enabled. While the number of subjects with profile scaling is small, there is no suggestion of any harm resulting from having profile scaling enabled.

	Without profile scaling (CI532 Benchmark Study) N=96	With profile scaling (Profile scaled in the control arm [CI632] of the CI632DEX Study) N=7
CNC words in quiet (% correct)		
Baseline#		
N	96	6
Mean (SD)	14.6 (11.60)	14.2 (15.8)
Median	14.0	9.0
Minimum, maximum	0.0, 40.0	0.0, 36.0
6 months		
N	96	6
Mean (SD)	60.9 (21.09)	82.8 (12.1)
Median	63.5	85.0
Minimum, maximum	3.0, 95.0	61.0, 94.0
Change from baseline		
N	96	6
Mean (SD)	46.3 (22.55)	68.7 (18.4)
Median	47.0	68.5
Minimum, maximum	-7.0, 90.0	48.0, 93.0

Table 25: CNC word recognition at 6 months postactivation

Conclusion

While the sample size with profile scaling is small, the improvements in CNC words in quiet observed at 6 months post-surgery suggest that profile scaling did not have a detrimental effect on word recognition in quiet. These findings support the view that profile scaling does not negatively impact speech understanding.

Literature review

A recent literature review strengthens the evidence that profile scaling does not compromise hearing performance in quiet or noisy environments. Six studies were analysed, encompassing both adults (Botros & Psarros, 2010[3]; Botros et al., 2013[2]; Vroegop et al., 2017[6]; Müller-Deile et al., 2021[4]; Roux-Vaillard et al., 2020[5]) and children (Bakhshinyan & Sataeva, 2018[1]). The studies compared clinical outcomes of cochlear implant (CI) programming using profile scaling against conventional methods. The findings consistently showed no statistically significant differences in speech perception between conventional MAPs and those using profile scaling, both in quiet and noisy environments (Botros et al., 2013; Müller-Deile et al., 2021; Vroegop et al., 2017). Interestingly, studies investigating participant preferences revealed a trend towards favouring profile scaling MAPs. Participants either preferred the profile-scaled MAP (or rated its sound quality higher) compared to the conventional one (Botros & Psarros, 2010; Vroegop et al., 2017), or reported no significant difference between the MAPs (Botros et al., 2013). Collectively, these studies provide strong evidence, with a high degree of certainty, that using profile scaling in CI programming compared to conventional methods does not negatively impact speech understanding in quiet or noisy environments. Furthermore, it suggests potential benefits in terms of user preference and sound quality perception.

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Conclusion

Combining these clinical studies and the review of literature offers strong evidence that the profile scaling algorithm does not negatively impact cochlear implant performance.

Notes

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