

Original research paper

# Conversion of adult Nucleus<sup>®</sup> 5 cochlear implant users to the Nucleus<sup>®</sup> 6 system

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**Objectives:** Cochlear's new sound processor system (Nucleus<sup>®</sup> 6) features a new noise reduction algorithm called SNR-NR (signal-to-noise ratio), and an environmental classifier called SCAN, which activates the appropriate sound coding algorithms for a given listening environment. In addition, the sound processors (CP910 and CP920) have a data logging feature with data visually summarized using clinical programming software and come with two remote controls, CR210 and CR230. The objective of this clinical study was to conduct a field acceptance study comparing the user experience with the Nucleus<sup>®</sup> 6 to the Nucleus<sup>®</sup> 5 system and to evaluate the benefits of Nucleus<sup>®</sup> 6 in an adult population currently equipped with the previous generation Nucleus<sup>®</sup> 5 sound processor. Our primary objective was to compare speech recognition in speech-weighted noise using Nucleus<sup>®</sup> 6 with SCAN (activating SNR-NR) with the default Nucleus<sup>®</sup> 5 'Noise' Program. Secondary objectives included comparisons of speech recognition in quiet, subjective performance feedback via questionnaires and diaries, and recipient preference for device and program type.

**Methods:** A prospective controlled trial was conducted with 30 adult Nucleus CI recipients using the Nucleus<sup>®</sup> 5 sound processor (condition A). The Nucleus<sup>®</sup> 6 sound processor (condition B) was evaluated in a within-subject ABBA design, with repeated speech in noise ( $S_0N_0$ , LIST sentence test), and speech in quiet testing ( $S_0$ , NVA words). The remote controls were randomly given during the two B intervals. In addition, recipients had to complete questionnaires and diaries on the use of their current as well as new sound processors and remotes.

**Results:** The group mean speech reception threshold in noise ( $SRT_{50}$ ) with Nucleus<sup>®</sup> 6 SCAN was significantly better (1.2 dB SNR) than with the Nucleus<sup>®</sup> 5 'Noise' Program. Mean speech recognition scores in quiet were not significantly different between the processors. Subjective performance feedback (APHAB) did not show a significant difference between Nucleus<sup>®</sup> 6 and Nucleus<sup>®</sup> 5 with high satisfaction scores being reported for both sound processors. Recipients preferred the SCAN program in noise and reported a clear overall preference for the Nucleus<sup>®</sup> 6 system. Clinicians were satisfied with the conversion process from Nucleus<sup>®</sup> 5 to Nucleus<sup>®</sup> 6.

**Discussion and conclusion:** SNR-NR provides a significant benefit in noise. Recipients were easily converted from Nucleus<sup>®</sup> 5 to Nucleus<sup>®</sup> 6 requiring little or no sound quality adjustment period. The Nucleus<sup>®</sup> 6 SCAN program was well accepted by the majority of recipients for use during their daily life.

## Introduction

In 2013, Cochlear<sup>™</sup> released the Nucleus<sup>®</sup> 6 system, which incorporates new sound processor technology. Two sound processors are available; the CP910 with an accessory socket for plug-in audio accessories, and the CP920, which is more compact and does not have an accessory socket. These two sound processors are otherwise functionally identical. In addition to new sound processor hardware, two new remote

controls are available: a small, basic remote (CR210), which allows volume or sensitivity adjustments, program changes and tele-coil activation, and a fully featured remote assistant (CR230) with diagnostic capabilities – particularly useful for parents of implanted children.

Four particular features differentiate Nucleus<sup>®</sup> 6 from the previous generation Nucleus<sup>®</sup> 5 system: Nucleus<sup>®</sup> 6 incorporates a new generation of input processing technology (Wolfe *et al.*, 2011) called SmartSound iQ (SSiQ). SSiQ includes a new background noise reduction algorithm for stationary

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noises (SNR-NR), wind noise detection and reduction (WNR), and an automatic scene classifier (SCAN). SCAN provides automatic detection of the user's listening environment and automatically selects appropriate input processing, thereby eliminating the need for multiple processor programs and manual program changes. In addition, data about scene, program use, and various other auto-diagnostic states are logged by the processor such that they can be visualized by the clinician during the following programming session.

SNR-NR acts instantaneously to reduce background noise levels irrespective of their direction, while retaining speech and other important signals (Hersbach *et al.*, 2012; Mauger *et al.*, 2012). The SNR-NR algorithm detects the background noise level in each frequency channel, estimates the signal-to-noise ratio (SNR) in each and then attenuates those channels having low SNRs (Loizou *et al.*, 2005).

WNR uses a differential analysis of the dual microphone input signals to identify wind noise; when detected, specifically designed multichannel compressors are activated to reduce the low-frequency wind noise while retaining other sounds to optimize the intelligibility of speech. A pilot study evaluating wind noise reduction in the Nucleus cochlear implant sound processors indicated positive speech understanding and listening quality results (Goorevich *et al.*, 2012).

SCAN analyzes microphone input signals and classifies the sound environment into one of six scenes (Speech in Noise, Speech, Noise, Wind, Quiet and Music). For each scene, SCAN selects the most appropriate microphone directionality and activates input processing based on the determined listening environment. Changes in settings are transitioned smoothly to avoid any abrupt or disruptive listening percept for the recipient (Case *et al.*, 2011).

The sound processor records how often certain scenes are detected by SCAN, how often manual program changes are initiated and the frequency of certain processor state warnings. This can provide valuable information for the clinician for the purpose of troubleshooting, counseling and program optimization for the recipient. For example, the average daily use of the processor in hours can be displayed, and whether the user is more often listening in noisy rather than quiet environments.

This study was conceived as a field acceptance study to determine if the requirements of the Nucleus<sup>®</sup> 6 are met when used by the end user. The objective of this study was to evaluate the incremental benefits of Nucleus<sup>®</sup> 6 for adult cochlear implant recipients currently using the Nucleus<sup>®</sup> 5 system (CP810 sound processor and CR110 remote assistant). The study

included speech testing in quiet and noise and usability measures collected via questionnaires and diaries over a period of 3 months. The benefits of wind noise reduction were not evaluated objectively in this study.

The primary objective of this study was to confirm in a clinical setting that the SNR-NR algorithm provides significant speech in noise recognition benefits in stationary noise as previously demonstrated by Hersbach *et al.* (2012). We hypothesized that speech recognition thresholds in speech-weighted noise (SWN; SRT50) would be significantly lower using a Nucleus<sup>®</sup> 6 processor with SNR-NR active, than those using Nucleus<sup>®</sup> 5.

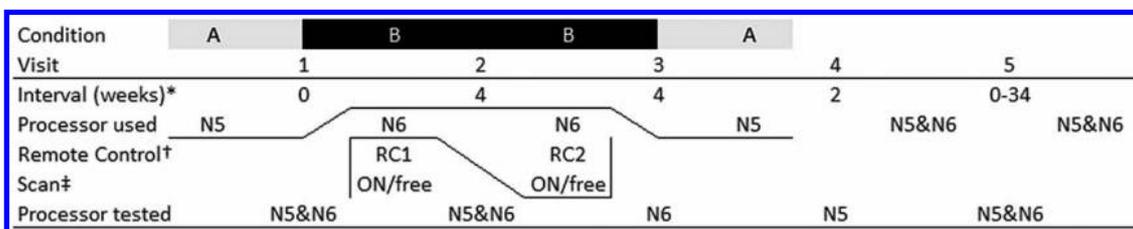
Secondary objectives evaluated sound processor preference (Nucleus<sup>®</sup> 6 versus Nucleus<sup>®</sup> 5), and Program preference (SCAN program versus Everyday), feedback on remote control usage, speech recognition in quiet, subjective performance from APHAB questionnaire (Cox and Alexander, 1995) and device use collected via custom questionnaires and diaries. In addition, we obtained feedback from clinicians, including their reactions to the new usage-logging functionality.

## Methods

A total of 30 cochlear-implanted recipients were recruited from and tested at two sites. Mean age was 48.3 years (SD 22.5). Mean duration of deafness prior to first-ear implantation was 18.5 years (SD 14.2). Mean duration of implant use was 4.7 years (SD 2.4). Five subjects had bilateral implants. Three of these received a CP900 series processor for both ears and were tested using bilateral Nucleus<sup>®</sup> 6 versus bilateral Nucleus<sup>®</sup> 5. The other two received a single CP900 series processor and were tested unilaterally with Nucleus<sup>®</sup> 6 versus Nucleus<sup>®</sup> 5. All recipients had greater than 40% LIST sentence test scores in 10 dB SNR noise prior to conversion, and were able to complete the speech tests used in this study.

## Study visit schedule

Figure 1 gives a summary of the study schedule with five visits and an ABBA protocol. Patients were tested in two conditions, namely with a Nucleus<sup>®</sup> 5 processor (condition A) or a Nucleus<sup>®</sup> 6 processor (condition B). They had been using the Nucleus<sup>®</sup> 5 processor (condition A) for at least 4 weeks before the first visit (visit 1 in Table 1). This processor was then replaced with the Nucleus<sup>®</sup> 6 processor (condition B) for two 4-week periods. They were then switched back to N5 (condition A) for 2 weeks and re-tested. The two 'condition B' periods were meant to test two different remote controls (see further). After visit 4, the patients received both processors for some time before they were asked to express their



**Figure 1** Study schedule and conditions \*Interval between the current and the previous visit. †RC1 = CR210 or CR230; RC2 = CR230 or CR210, respectively. ‡ON/free: users were asked to use the SCAN mode for 2 weeks and then they were left free to switch between SCAN or fixed mode to their liking.

ultimate preference. Speech recognition tests were performed at each visit. This allowed us to control not only for processor condition effect but also for learning effects since both processors were tested after a period of non-use, a 2–4 and a 4–8 weeks take home experience. At the final study visit, all subjects were re-tested with both devices.

At visit 1, 15 recipients received the CR210 remote and the other 15 recipients the CR230 remote. Recipients were instructed to use the SCAN program during the first 6 days of use. A Fixed program (ASC and ADRO only, with SCAN disabled) could be used after the first six days and at the user’s discretion.

At visit 2 the recipient crossed over to use the CR230/CR210 remote. Again recipients were instructed to use the SCAN program during the first 6 days of use.

Questionnaires for sound processor and remote control use were provided at the end of session 12.

**Table 1** Summary of sound coding parameters used by subjects

Parameter	Value	N
Nucleus® 6 processor type	CP910	15
	CP920	18
Strategy	ACE	31
	MP3000	2
Active electrodes	22	14
	21 (2–22)	3
	20 (1–22; 1; 3–22: 2)	3
	19 (2–5 & 8–22: 1; 4–22: 3)	4
	18 (5–22)	6
	16 (3–5 & 10–22: 1; 5–22: 1)	2
Simulation rate/channel (pps)	13 (3–5 & 10–22)	1
	500	6
	720	6
	900	20
Pulse width per phase (µs)	1200	1
	25	29
	37	1
	50	3
Number of maxima	6	2
	8	4
	10	3
	11	1
	12	2
	14	20
	15	1

At visit 3 after testing, the CP900 processor was retrieved and the recipients sent home with only their Nucleus® 5 system.

At the end of visit 4, subjects were re-issued with Nucleus® 6 and counselled to use whichever processor they wished for a further period of home use.

The timing of the fifth study visit was scheduled to coincide with the availability of the commercial Nucleus® 6 system, which replaced the investigational version of the study and which the recipients could keep afterwards. Eleven of the recipients received their commercial system at the end of visit 4, hence data collection for visits 4 and 5 were combined in one visit.

**Sound processor programing**

Prior to starting the study, all subjects actively used the Nucleus® 5 sound processor (CP810) for a minimum of 1 month and programed with the default sound processor programs that incorporated the Smartsound features Automatic Sensitivity Control (ASC) and Adaptive Dynamic Range Optimization (ADRO) (James *et al.*, 2002, Müller-Deile *et al.*, 2008).

Nucleus® 6 sound processor programs used the same coding parameters as for Nucleus® 5, such as summarised in Table 1.

**Speech testing**

Speech test were performed with Nucleus® 5 (visit 4) or Nucleus® 6 processors (visit 3) or both (visits 1, 2 and 5). To avoid order effects the order of processor condition was randomized across recipients for visits 1, 2 and 5. Contralateral devices (hearing aids or Freedom processors) were removed for testing. All subjects had severe to profound hearing loss (Pure Tone Average of 85 dB or worse) at the contralateral side. In the few cases with unaided thresholds of 70 dBHL or better, that ear was plugged during testing.

The speech in noise tests for Nucleus® 5 were conducted using the SmartSound ‘Noise’ Program (ASC, ADRO and Zoom activated), and for Nucleus® 6 using SCAN (ASC, ADRO, Zoom and SNR-NR).

For the first 15 subjects, during visits 1–4, speech recognition scores in noise were obtained with a

fixed speech and noise level for two randomized sentence lists per processor condition per visit. Speech recognition in noise was measured with the Flemish sentences-in-noise test (LIST, van Wieringen and Wouters, 2005, 2008). Speech and SWN (source LIST sentences recording) was presented from the front ( $S_0N_0$ ). Speech was presented at 70 dB SPL and the noise level chosen per subject between 0 and 10 dB SNR, with the aim to limit ceiling or floor effects (mean SNR 4.0 dB, SD 4.1).

For the last 15 subjects the LIST test was performed adaptively during visits 1–4 with speech fixed at 65 dB SPL while noise level was adjusted. The adaptive procedure allowed determination of the SNR level at which the whole sentence recognition score is approximately 50% (SRT<sub>50</sub>, van Wieringen and Wouters, 2008). Two SRT50 estimates were obtained per processor condition per visit.

All 30 subjects were tested in visit 5 using the adaptive SNR procedure, with two lists/estimates per processor condition.

A trial list of sentences was delivered prior to the start of noise testing with SCAN to ensure that the speech in noise scene was activated appropriately, and the time interval between lists was minimized to maintain this setting during testing. The SCAN setting was monitored and verified during testing using the bidirectional communication of the CR230 remote.

Speech recognition in quiet was measured with the Flemish recordings of the Dutch word test (NVA test, Wouters *et al.*, 1994) using two random-order word lists per processor condition. For Nucleus<sup>®</sup> 5, the test was conducted using the SmartSound ‘Everyday’ Program (ASC and ADRO), and for Nucleus<sup>®</sup> 6 the Fixed program was employed with the same settings (ASC and ADRO only, with SCAN disabled). Speech was presented from the front ( $S_0$ ) at 50 dB SPL and word-lists were randomized among visits and recipients.

### Questionnaires

Feedback from the recipients was collected during visits 1, 2 and 3 with customized Nucleus<sup>®</sup> 5 and Nucleus<sup>®</sup> 6 questionnaires exploring processor usability, functionality, subjective performance and preference. Subjects were also provided with a diary (see Appendix 1) to evaluate the daily use of the Nucleus SCAN program. The first part of the diary had to be completed during the first 6 days following visits 1 and 2, and while using the SCAN program only. The questionnaire included six statements related to hearing performance, and recipients had to indicate daily to what extent they agreed or disagreed with these statements. The second part of the questionnaire, to be completed in the following 4 days, asked subjects

which program (SCAN or Fixed), they used in various situations. In addition, the APHAB questionnaire was administered at visit 1 for Nucleus<sup>®</sup> 5 and visit 2 for Nucleus<sup>®</sup> 6 to identify subjective performance differences.

Clinicians completed customized questionnaires on Nucleus<sup>®</sup> 6 usability and functionality.

### Electronic data

Anonymous and encrypted export files from the Custom Sound database (.cdx files) were collected at visits 1, 3 and 5 and sent to Cochlear via email. These exports contained data logged by the Nucleus<sup>®</sup> 6 processor. The data log analysis became available at the end of the study when the commercial version of the programming software was released.

### Statistical analysis

Per cent correct scores and SNR50 ( $N = 15$ ) collected at visits 1–4 were analysed using two-way, repeated-measures analysis of variance (ANOVA) with processor condition and visit as factors. A separate one-way ANOVA was performed to compare SNR50 in visit 5 ( $N = 30$ ) between the N5, and the investigational and commercial N6 processors. Holm-Sidak corrections were used for multiple planned comparisons.

APHAB scores were analysed using paired *T* tests for each subscale: ‘Ease of Communication’, ‘Background Noise’, ‘Reverberation’ or ‘Aversiveness’. For non-normally distributed data, non-parametric tests were used.

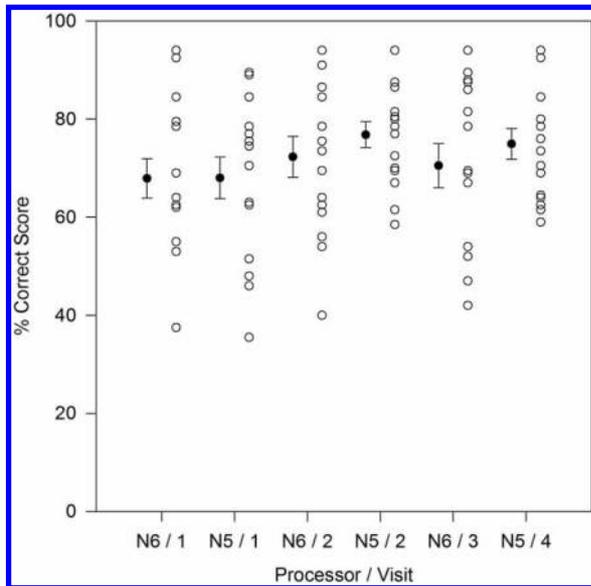
Preference data for Nucleus<sup>®</sup> 6 SCAN versus the Nucleus<sup>®</sup> 6 (No SCAN) in noise was analysed with Chi-squared test.

### Ethics

This clinical study was sponsored by Cochlear AG (Basel, Switzerland) and conducted in accordance with ISO14155-2011 (clinical investigation of medical devices for human subjects – good clinical practice) and the Declaration of Helsinki (date). Regulatory approval was obtained by the sponsor, and the participating centres obtained Ethics Committee approvals before for the start of the investigation. All implant recipients participating in this study signed a written informed consent prior to any study-related examination or activity. All recipients enrolled in the study were stable daily device users and corresponding Adverse Events were to be recorded during study visits.

### Results

No adverse events were reported. Eight device deficiencies were reported but were resolved through further instruction of recipients or replacement of the deficient part or device.



**Figure 2** Speech in Noise Results with CP900 (N6) and CP810 (N5) using the LIST sentence test (SNR fixed, visits 1–4, *n*: 15). Solid points are group means. Error bars indicate standard errors of the means and open points are individual data. A higher point on the graph indicates a superior score.

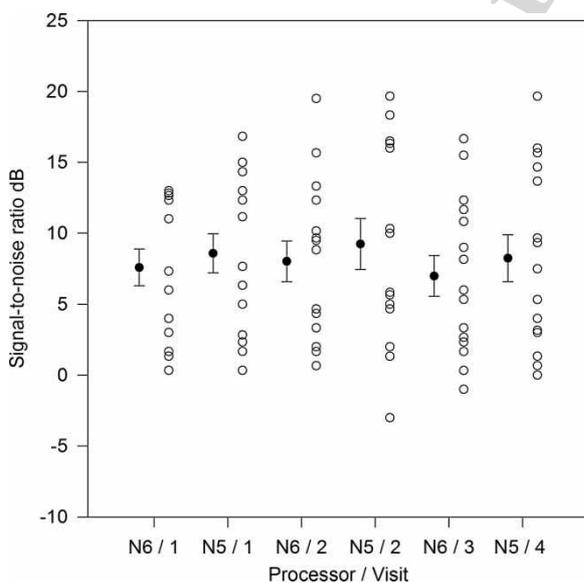
Per cent correct scores for speech recognition in noise with fixed individualized SNR are shown in Fig. 2. SNRs ranged from 0 to 10 dB. Scores for Nucleus® 5 ranged from 53% to 90% across subjects and visits; in many cases scores approached ceiling levels. A repeated-measure two-way ANOVA (RM-ANOVA) was performed on per cent correct scores with factors being processor (Nucleus® 5 and Nucleus® 6) and visit (Nucleus® 6 visit 3 equated to

Nucleus® 5 visit 4). There was no significant main effect of processor ( $F(1, 14) = 1.802, P = 0.201$ ) but a significant effect of visit ( $F(2, 28) = 3.967, P = 0.030$ ). There was no statistically significant interactions between processor and visit ( $F(2, 28) = 0.759, P = 0.478$ ).

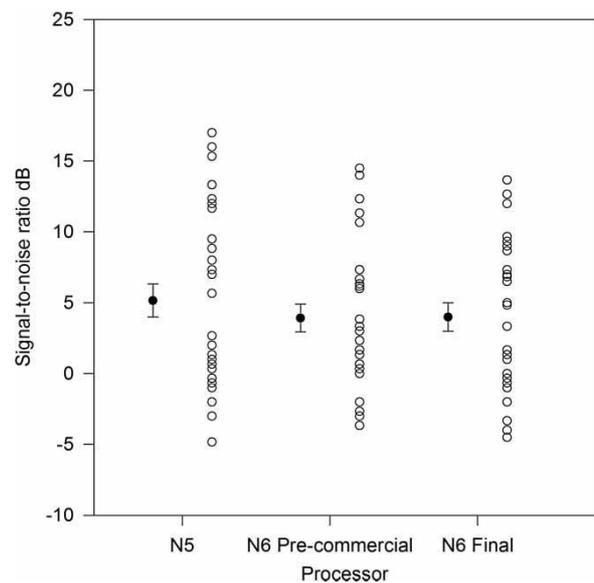
Scores were significantly greater for visit 2 compared to visits 1 and 2 (68.0% versus 74.6%,  $P = 0.032$ , Holm-Sidak). Thus some learning effects occurred.

Speech recognition thresholds in noise for visits 1–4 are summarized in Fig. 3. A RM-ANOVA was performed on dB SNR with factors processor (Nucleus® 5 and Nucleus® 6) and visit (Nucleus® 6 visit 3 equated to Nucleus® 5 visit 4). There was a trend for SNRs with Nucleus® 6 to be lower/better than those for Nucleus® 5 ( $F(1, 14) = 3.762, P = 0.073$ ); and no effect of visit ( $F(2, 28) = 1.621, P = 0.216$ ). There was no statistically significant interaction between processor and visit ( $F(2, 28) = 0.049, P = 0.952$ ). Across the three visits least mean scores for each processor were 8.7 dB SNR for Nucleus® 5 and 7.5 dB SNR for Nucleus® 6 with an SEM of 0.42 dB SNR.

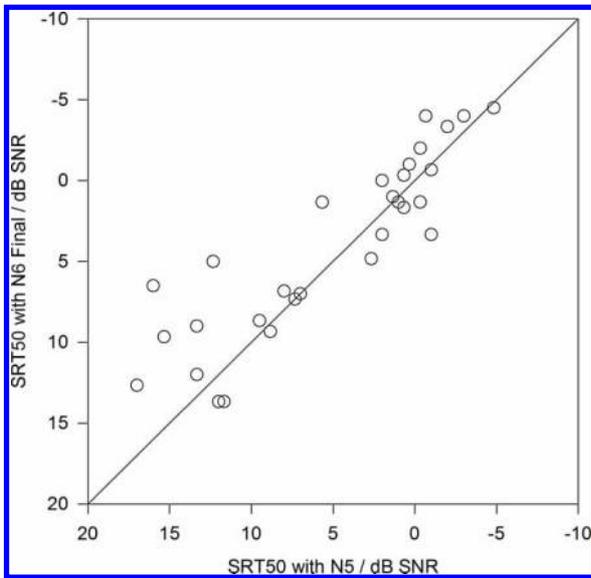
Speech recognition thresholds in noise comparing Nucleus® 5, the investigational version of Nucleus® 6 and the commercial of Nucleus® 6 for the entire study population ( $N = 30$ ) are shown in Fig. 4. A single-factor RM-ANOVA with processor as factor was performed on dB SNR. There was a significant effect of processor ( $F(2, 58) = 4.823, P = 0.012$ ). Post hoc Holm-Sidak comparisons revealed that mean dB SNR for both investigational and commercial versions



**Figure 3** Speech in Noise Results with CP900 (N6) and CP810 (N5) using the LIST sentence test in SWN (SNR adaptive, visits 1–4, *n*: 15). Solid points are group means. Error bars indicate standard errors of the means and open points are individual data. A lower point on the graph indicates a superior score.



**Figure 4** Speech in Noise Results with CP900 (N6) and CP810 (N5) using the LIST sentence test in SWN (SNR adaptive, visit 5, *n*: 30). Solid points are group means. Error bars indicate standard errors of the means and open points are individual data. A lower point on the graph indicates a superior score.



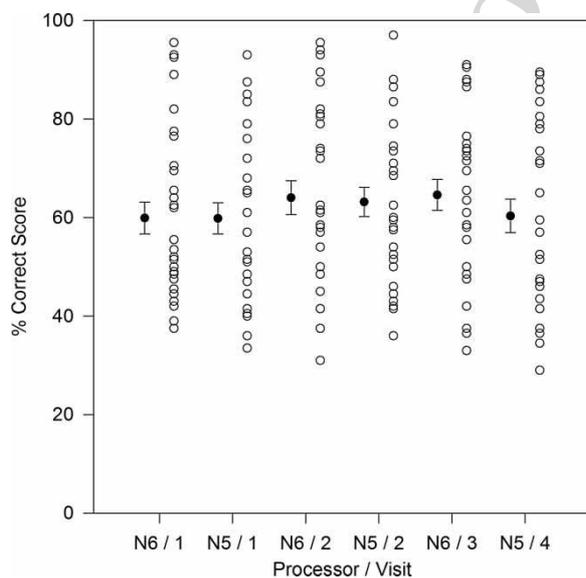
**Figure 5 Comparison of SRT50 results using CP900 (N6), in its final configuration, versus CP810 (N5).**

of Nucleus<sup>®</sup> 6 were significantly lower/better than for Nucleus<sup>®</sup> 5 (1.2 dB,  $P = 0.023$  in both cases).

SNRs for Nucleus<sup>®</sup> 5 were on average lower for visit 5 compared to visits 1–4 for the 15 subjects tested using the adaptive LIST (best SNR 8.2 dB in visit 4 versus 7.8 for visit 5). Most of the improvement/reduction in SRT50 appeared to occur for subjects with poorer/higher dB SNR (Fig. 5).

Fig. 6 presents the speech-in-quiet results obtained with the NVA test for visits 1–4.

An RM-ANOVA was performed on per cent correct NVA scores with factors processor (Nucleus<sup>®</sup> 5 and



**Figure 6 Speech in Quiet Results CP900 (N6) and CP810 (N5) using the NVA test (visits 1–4,  $n = 30$ ). Solid points are group means. Error bars indicate standard errors of the means and open points are individual data. Higher points on the graph indicate superior scores.**

Nucleus<sup>®</sup> 6) and visit (Nucleus<sup>®</sup> 6 visit 3 equates to Nucleus<sup>®</sup> 5 visit 4). There was no significant main effect for processor ( $F(1, 29) = 3.565, P = 0.069$ ) but there was for visit ( $F(2, 58) = 5.167, P = 0.009$ ). There was no statistically significant interaction between processor and visit ( $F(2, 58) = 1.869, P = 0.163$ ). Scores were significantly different between visits 1 and 2 (59.9% versus 63.6%,  $P = 0.008$ ) but not for visit 3/4 (62.4%, SEM 0.84%), again indicative of some learning effects occurring in the early stages of the study.

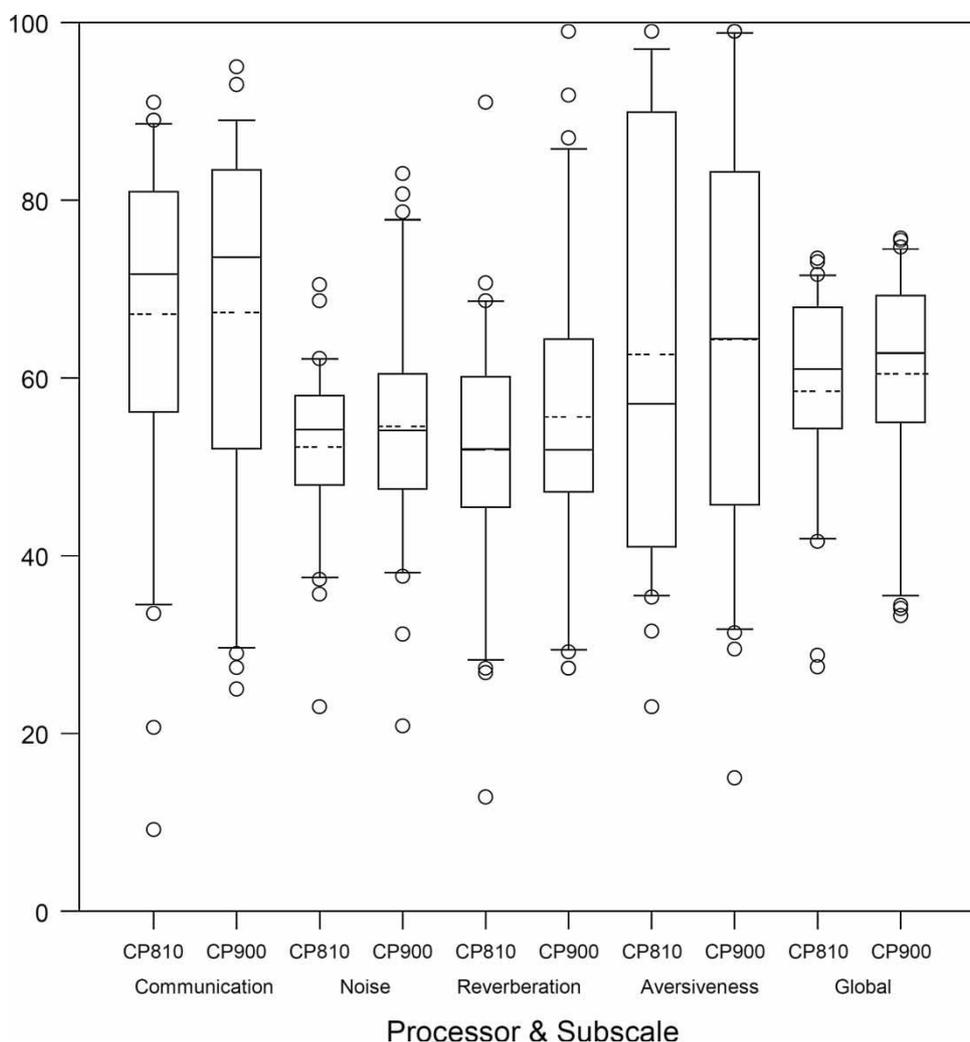
The APHAB global and subscale scores (Communication, Noise, Reverberation, Aversiveness) for Nucleus<sup>®</sup> 5 in visit 1 and Nucleus<sup>®</sup> 6 in visit 2 are shown in Fig. 7. Signed-rank tests were performed where paired differences were not normally distributed. There were no significant differences between Nucleus<sup>®</sup> 6 and Nucleus<sup>®</sup> 5 scores for Communication (Wilcoxon signed-rank test,  $P = 1.00$ ), Noise (paired Student's  $t$  test,  $P = 0.27$ ), Reverberation (paired Student's  $t$  test,  $P = 0.19$ ), Aversiveness (Wilcoxon signed-rank test,  $P = 0.30$ ), and global scores (Wilcoxon signed-rank test,  $P = 0.13$ ).

The group outcomes of the first and second diary did not vary substantially, and were summed. Fig. 8 presents the outcomes of the first part of the diary showing that overall 48% of the recipients agreed with the six statements favouring the use of SCAN while about 34% were neutral and about 17% of the recipients disagreed with the statements.

The most favourable statement was 'I could hear important sounds in my environment at comfortable levels' and the least favourable statement was 'Sounds coming from different directions sounded normal'.

The second part of the diary was completed over the past 4 days during which the recipients were allowed to switch between the SCAN and the Fixed program.

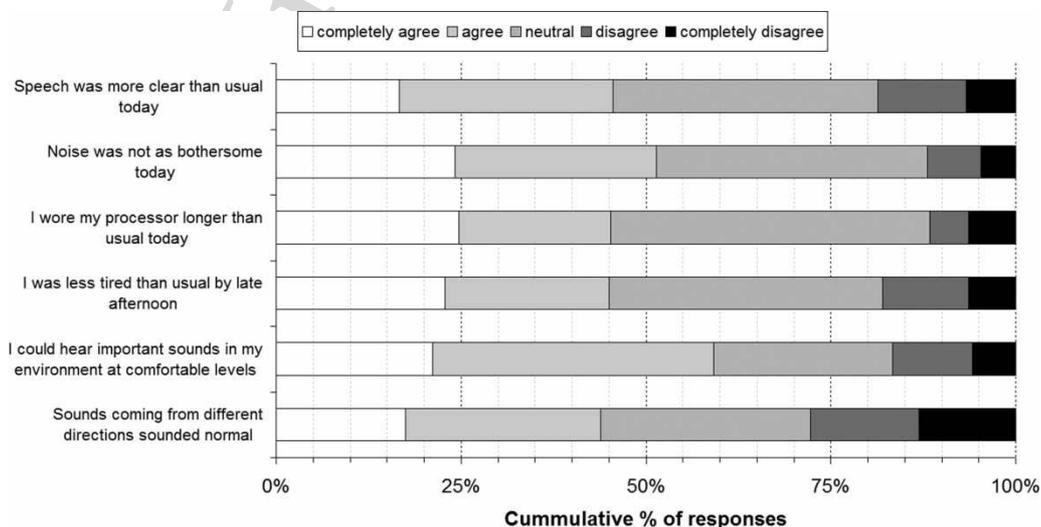
Between visits 1 and 2, 60% of subjects reported that they could tell the difference between SCAN and Fixed programs and overall 60% used the SCAN program most of the time. Of those who could tell the difference about 50% used the SCAN program most of the time and 10% used SCAN and the Fixed program about equally. Similar reports were given at visits 2 and 3. For those subjects who reported using both programs consistently, the pattern of program use across the situations mentioned in the Diary changed between visits 1–2, and 2–3. Initially these subjects switched to use the Fixed program more of the time (70%), however later they switched to using the SCAN program the majority of the time (70%). This indicates that some acclimatization to the SCAN program was required. Notably these subjects initially preferred the Fixed program for 'I want to



**Figure 7** Results obtained with the APHAB questionnaire. Solid points are group means. Error bars indicate standard errors of the means and open points are individual data. A higher score indicates a higher percentage of hearing problems reported by the person.

be comfortable' and 'I want to be sure I know where sound is coming from' but gradually preferred SCAN in these situations. Interestingly, these subjects

generally continued to use the Fixed program for 'Listening to quiet sounds'. In personal communications with the clinicians, some recipients reported



**Figure 8** Diary outcomes with recipient's feedback on the first 6 days of using SCAN.

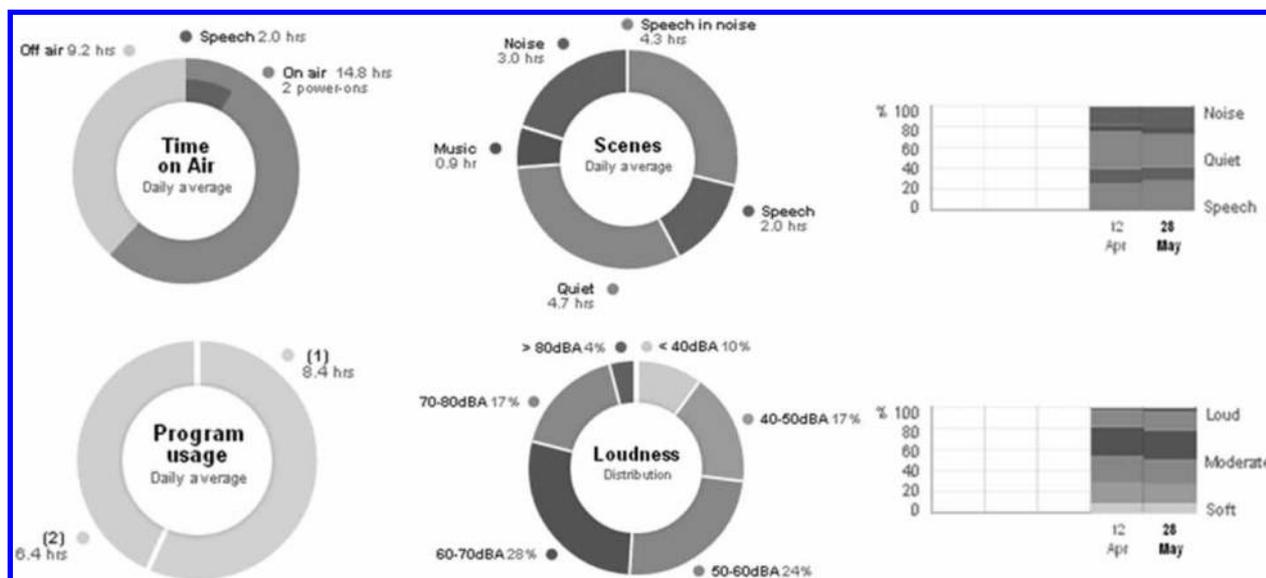


Figure 9 Usage Logs – example of the ‘donut’ display in the Custom Sound fitting software.

that in noise, the SCAN program comfortably adapts and attenuates the background noise. One recipient reported that with SCAN, the TV without subtitles could be followed, while another recipient reported that she could follow the radio while in the car.

**Subjective preference**

Recipient preference for sound processor was evaluated at the second study visit. After 4 weeks of take home use, 14 recipients (47%) reported preferring the Nucleus® 6 CP900 processor, 14 recipients (47%) equally preferred the two processors, and two recipients (7%) preferred Nucleus® 5.

The recipient’s preference for the two Nucleus® 6 programs was also obtained for quiet and noise conditions. The SCAN program was preferred by the majority of recipients in quiet (60%) and in noise (63%) while approximately 30% reported a preference for the program with SCAN disabled. An additional 10% of recipients reported an equal preference for the two programs in quiet or in noise. Two separate 1-sample proportions test with continuity corrections were performed to test the hypotheses that equal or more recipients prefer the SCAN program over the non-SCAN program. Proportions for preference for ‘Non-SCAN’ over ‘SCAN’ were compared to the Null hypothesis proportion  $\geq 0.5$ . Proportions for “no preference” were discarded. In quiet, the proportion of recipients preferring ‘Non-SCAN’ was not significantly lower than 0.5 ( $\chi^2(1) = 2.37, P = 0.062$ , proportion 0.33, 95% confidence interval 0–0.51). In noise, the proportion of recipients preferring ‘No SCAN’ was significantly lower than 0.5 ( $\chi^2(1) = 3.70, P = 0.027$ , proportion 0.296, 95% confidence interval 0–0.47). Thus SCAN was rated as equal to Non-SCAN or preferred over Non-Scan in a significantly

higher proportion of subjects for noise ( $P < 0.05$ ), and there was a trend for the same outcome in quiet ( $P < 0.10$ ).

At visit 3, recipient’s preference for the two Nucleus® 6 remotes was evaluated and data obtained for 27 subjects. Preferences were split evenly across devices, with 27% preferring the CR210 and 27% preferring CR230. The remaining 46% of the recipients equally preferred the two remote devices. When equipped with the CR230, 17 recipients were programmed in Advanced Mode and 13 recipients in Simple Mode. When equipped with the CR210, 25 recipients had Volume enabled and 2 recipients had Sensitivity enabled.

At the final study visit all recipients elected to transfer the remaining warranty on their Nucleus® 5 processor over to the Nucleus® 6 processor suggesting that they will continue to use the Nucleus® 6 processor as their primary hearing device (or devices for the 3 bilateral recipients) in their daily life.

**Usage logging**

Recipient’s Usage data was automatically captured and uploaded to the Custom Sound software database each time the sound processor was connected for programming. Fig. 9 shows a summary of the usage data from the time of last connection displayed in Custom Sound. The most recent data are presented in ‘donuts’ and historical data are summarized in a 100% stacked column chart (see Fig. 8).

Complete Usage Logs were collected for 15 recipients. The average total ON-time in hours and the distribution of hours spent by the recipient in different Scenes is displayed in Fig. 10. On average, recipients were wearing their Sound Processor 10 hours/day, ranging from 5 to 17 hours/day.

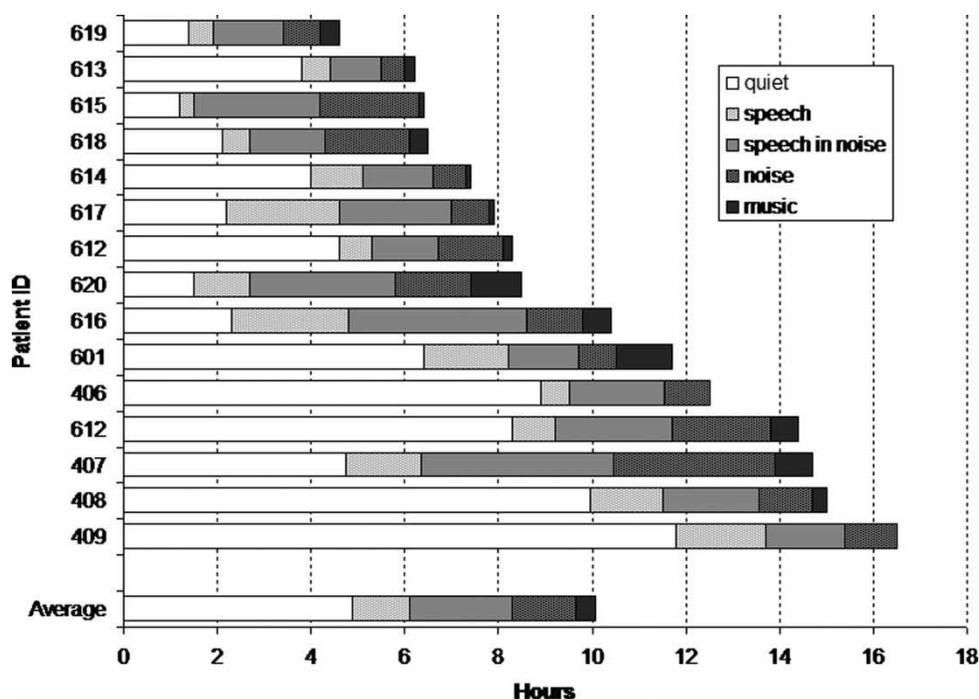


Figure 10 Usage Logs – daily averages/scenes (n: 15).

### Discussion

The primary objective of this study was to assess the effects of the Nucleus® 6 SCAN program in background noise. This program automatically activates a digital SNR-NR algorithm to reduce stationary background noise, and this was compared against the performance of the Nucleus® 5 processor using a manually selected SmartSound ‘Noise’ Program.

Evaluation of 30 subjects with SCAN failed to show a significant benefit over Nucleus® 5 in quiet or using a fixed level noise test (due to ceiling effects), however, when administered adaptively, noise testing showed a statistically significant effect for Nucleus® 6 SCAN over Nucleus® 5 ( $P = 0.023$ , benefit 1.2 dB, Fig. 3) in SWN. Since neither the CI recipients nor the assessors were blinded, it cannot be entirely ruled out that some bias in favour of the new device may have to be taken into account. An improvement of 1.2 dB SRT is generally considered clinically relevant. The psychometric function of the speech test used (LIST in noise) has a slope of 17%/dB (van Wieringen and Wouters, 2008), which means that a 1.2 dB improvement stands for a 20.4% increase in intelligibility.

Clinicians reported that recipients were easily converted from Nucleus® 5 to Nucleus® 6, requiring little or no adaptation time to the new sound processor.

Subjective hearing performance outcomes showed no significant differences on the APHAB Global scale and subscales between Nucleus® 6 and Nucleus® 5, however, this may not have been a sensitive enough measure for evaluating differences in input processing technologies.

Customized questionnaires were also administered during the study and showed high levels of satisfaction with both the Nucleus® 6 and Nucleus® 5 processors. Recipients were least satisfied with hearing in difficult noisy listening environments. Feedback from daily recipient diaries compared hearing performance with SCAN versus No SCAN. Over half of the subjects responded favourably to SCAN despite usage logs showing that many recipients used their device in a predominantly ‘quiet’ environment. Some recipients provided additional comments suggesting increased comfort (decreased loudness) with SCAN, which could be attributed to the SNR-NR algorithm.

The majority of recipients preferred the SCAN program for listening in noise and in quiet, suggesting that SCAN is well accepted and suitable as a default option for the new programming software.

Clinicians indicated that approximately 40% of the recipients regularly (several times/day, once or twice/week) change programs, with 20% changing occasionally (once/twice/month), and the remaining approximately 40% never changing programs. SCAN offers an opportunity to easily and automatically benefit from enhanced sound coding without the need to change Programs.

About half of the recipients (14/30) reported a preference for the CP900 Sound Processor with the other half reporting no clear preference (14/30). All recipients transferred the remaining warranty on their CP810 Sound Processor over to the CP900 Sound Processor, indicating their preference for ongoing use of the new system as their primary processor.

Usage logging was received positively and rated by the clinicians as a useful tool to facilitate programming and counseling of recipients.

Clinicians can see in the Usage Logs how much time is spent in a high-quality speech only environment. In these environments one might expect best open set speech understanding and implicit learning to listen with the Cochlear implant. In addition to the presented data, Usage Logs include Volume and Sensitivity settings for different Programs and accessory usage. Usage Logs can be used by clinicians to counsel the recipient and make informed decisions on required changes in MAP parameters.

## Conclusion

This study confirms the benefit of a new noise reduction algorithm called ‘SNR-NR’ in cochlear implant recipients equipped with the Nucleus® 6 CP900 series sound processors.

Recipients were easily converted from Nucleus® 5 to Nucleus® 6 requiring little or no sound quality adjustment period.

The Nucleus® 6 SCAN program, which provides automatic selection and adjustment of different input processing options for a given listening situation, was well accepted by the majority of recipients for use during their daily life. Recipients clearly preferred the new system (Nucleus® 6) compared to their current system (Nucleus® 5), with all electing to continue use of the new processor at the conclusion of the study.

Usage logging, which is a new clinical tool that provides a visual summary of usage data collected by the processor, was received positively and rated by the clinicians as a useful tool to enhance programming and counseling of recipients.

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## Appendix 1: Diary

For each of the first 6 days after the programming session, subjects were asked to rate between ‘Completely Agree’ to ‘Completely Disagree’ using the linear analog scale below, for each of the following six questions:

Completely Agree/Completely Disagree

1. Speech was more clear than usual today.
2. Noise was not as bothersome today.

3. I wore my processor longer than usual today.
4. I was less tired than usual by late afternoon.
5. I could hear important sounds in my environment at comfortable levels.
6. Sounds coming from different directions sounded normal.

Over the following 4 days, subjects were instructed to freely select the SCAN or Fixed programs depending on what they were listening to.

They were then asked to circle the options (bulleted) that best matched their opinions:

I could tell the difference between the two programs on my processor.

- No (If you have circled No, you do not need to respond to the questions below)
- Yes (If you have circled Yes, please answer the questions below)

Circle the program that you used the most during the past 4 days.

- SCAN program
- Fixed program

I found the SCAN program better than the Fixed program when (circle all that apply)

- I never use the SCAN program 1.
- I’m trying to understand in a quiet environment.
- I’m trying to understand in a little noise.
- I’m trying to understand in a lot of noise.
- I’m tired.
- I want to be comfortable.
- I want to be sure to know where sound is coming from.
- I need to hear quiet sounds.
- I am in a variety of different listening situations.

For consistency the above propositions were repeated for the Fixed program:

I found the Fixed program better than the SCAN program when (circle all that apply).

## Disclaimer statements

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**Ethics approval** This clinical study was sponsored by Cochlear AG (Basel, Switzerland) and conducted in

accordance with ISO14155-2011 (clinical investigation of medical devices for human subjects – good clinical practice) and the Declaration of Helsinki (date). Regulatory approval was obtained by the sponsor, and the participating centers obtained Ethics Committee approval from the University of Ghent Ethical Committee before the start of the investigation. All implant recipients participating in this study signed a written informed consent prior to any study-related examination or activity. All recipients enrolled in the study were stable daily device users and corresponding Adverse Events were to be recorded during study visits.

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