

FOR PROFESSIONALS



Sound Processor Upgrades Evidence Summary

Improving patient and
professional outcomes

Contents

How new sound processor technology can improve patient hearing outcomes 5

Impact of new sound processor technology on patient satisfaction15

Creating sustainable care models and reducing clinic burden21

The health economic benefits of cochlear implants, including upgrades. 25

Appendix..... 30

 a. Speaker set ups for clinical tests of speech recognition in noise 30

 b. Cochlear™ sound processing technology over the years. 30

 c. Audiological abbreviations.31



Why upgrading a sound processor matters


As a clinician, you are ideally placed to understand the changing needs of your patients as you provide support and guidance throughout their hearing journey. In partnership with you, we are committed to improving patient hearing outcomes through innovation in sound processor technology and Connected Care solutions.

This document outlines key insights from clinical and economic studies supporting the benefits to cochlear implant (CI) patients of upgrading to the latest sound processor.


Peer reviewed, published research indicates that these benefits go beyond helping patients to improve their ability to hear¹⁻⁶ – they can positively impact their quality of life.⁷⁻¹⁰ For you, Connected Care innovations may bring efficiencies to your clinical practice and save your patients time and effort as well.¹¹⁻¹²

Cochlear implant treatment, including regular sound processor upgrades, has been shown to be cost-effective and beneficial to both patients and society.¹³⁻¹⁶


We have summarized the benefits into the following four categories:




Hearing outcomes



Patient satisfaction



Reduced clinic administrative time



Health economic benefits

We hope this document provides you with valuable information to support sound processor upgrade discussions with your patients.

“Immediately I could start hearing differences in sounds—the tiniest little whisper from the air conditioning or talking in conversations in other rooms.”

Solidea, Cochlear™ Nucleus® System recipient



How new sound processor technology can improve patient hearing outcomes

In our ever-changing world, staying connected has never been more important. And hearing well in different environments is often a challenge.

Our commitment to innovation means that each successive generation of sound processor harnesses new technology to deliver advances in noise reduction, automation, streaming, and wireless technologies designed to improve your patients' hearing outcomes.¹⁻⁶

The following studies demonstrate that even patients who have had their implant for more than 20 years may experience significant performance improvements today by accessing latest-generation sound processing technology.¹⁻⁶



Speech comprehension across multiple CI processor generations: Scene dependent signal processing.¹

Hey M, Böhnke B, Mewes A, et al.

Study design

In a single site, prospective German study, 20 post-lingually deafened adults aged between 31 – 76 years participated in a comparative study with three generations of Nucleus® sound processors (the Nucleus® 5, Nucleus® 6 and Nucleus® 7 Sound Processors). Participants had more than 5 years of cochlear implant experience with the Nucleus 5 or Nucleus 6 Sound Processor and scored at least 80% on the Oldenburg sentence test in quiet at 65dB SPL.

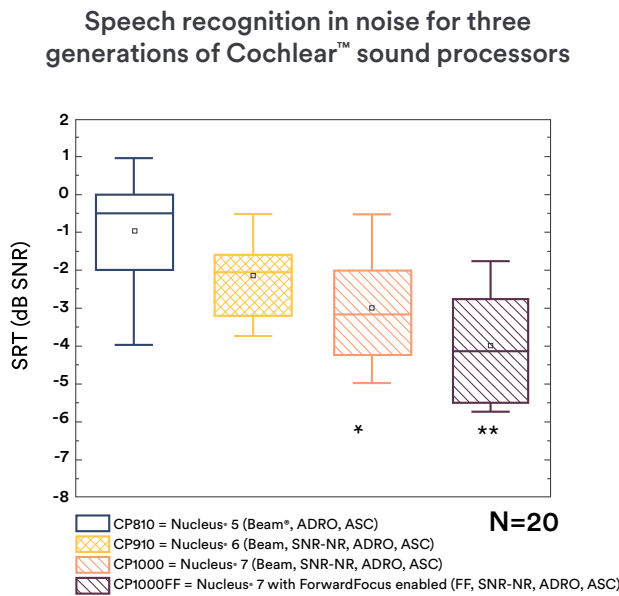
A take-home trial over several weeks involved randomized use of the Nucleus 6 and Nucleus 7 Sound Processors and fortnightly assessments. Speech recognition in quiet and noise was assessed using German word and sentence materials, presented from a single loudspeaker (S0, S0N0). The pre-processing technologies evaluated in noise are shown on the right.

Results

In noise, mean speech recognition scores with the Nucleus 7 Sound Processor without and with ForwardFocus[#] enabled indicated significantly lower SNR, i.e., **better hearing in more difficult listening situations, compared to the Nucleus 5 Sound Processor (p =0.01, p < 0.001, respectively). Compared to the Nucleus 6 Sound Processor, performance was significantly better with the Nucleus 7 Sound Processor with ForwardFocus activated (p <0.001).**

Conclusion

The Nucleus 7 Sound Processor, with ForwardFocus enabled, provided significant group performance benefits in noise compared to older generation sound processors.



Distribution of group speech recognition outcomes for sentences in noise (dB SNR) across different sound processors. Box and whisker plot shows median (central line), 25th and 75th percentile intervals (box limits), and 5th and 95th percentile intervals (whiskers). Mean values are shown as □. Lower dB SNR values indicate better speech reception thresholds. Asterisks represent significant differences between the Nucleus 7 Sound Processor vs the Nucleus 5 Sound Processor *p< 0.05; and the Nucleus 7 Sound Processor with ForwardFocus enabled vs the N6 and N5 Sound Processors ** p<0.001. Adapted from Hey et al. 2021.

With each successive generation of Nucleus® sound processors, hearing benefits are observed. Improved hearing performance, through features like ForwardFocus, is a key reason to recommend upgrading to next generation technology.



Contribution of noise reduction pre-processing and microphone directionality strategies in the speech recognition in noise in adult cochlear implant users.²

Goffi-Gomez MVS, Muniz L, Wiemes G, et al.

Study design

In a multi-center, prospective, acute Brazilian study, 47 post-lingually deafened adults participated in a comparison of the Nucleus® 7 Sound Processor and the Nucleus® 5 Sound Processor to determine the contribution of combining automatic noise reduction pre-processing strategies with fixed microphone directionality in the speech recognition in adult CI users. Participants were aged 19-70 years (median 43 years) and had 2 – 16 years (median 6 years) of CI experience. Inclusion criteria included a minimum score of 60% on the Brazilian-Portuguese Hearing in Noise Test with their Nucleus 5 Sound Processor in quiet.

For the single session testing, the patient's original Nucleus 5 Sound Processor programs were copied to a new Nucleus 5 Sound Processor and converted to a newly fitted Nucleus 7 Sound Processor. The ForwardFocus[#] feature was also enabled as an option on the Nucleus 7 Sound Processor. Evaluations used sentences in quiet at 65dB SPL, and in noise at fixed SNR of +10dB and in adaptive SNR (targeting 75% correct word scores), using a single speaker (S0, S0N0). In addition, a spatially-separated speech in noise setup (S0N180) was used at a fixed 0dB SNR to assess the Nucleus 7 Sound Processor with ForwardFocus enabled compared to the Nucleus 5 Sound Processor with Beam®.

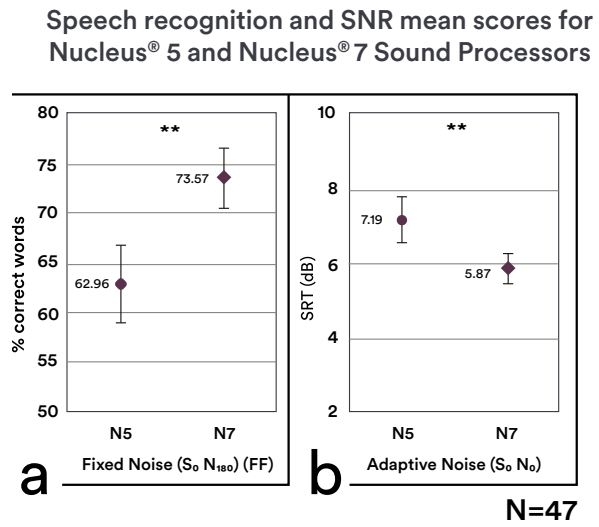
Results

In quiet, group mean speech scores were similar between the two sound processors. In noise with fixed SNR and adaptive SNR (S0N0), the mean speech scores were significantly better with the Nucleus 7 Sound Processor (p < 0.05).

Group mean speech recognition scores were significantly better for spatially-separated speech in noise (S0N180) with the Nucleus 7 Sound Processor with ForwardFocus enabled compared to the Nucleus 5 Sound Processor using Beam (p < 0.05).

Conclusion

The Nucleus 7 Sound Processor provided significant benefits for speech recognition compared to the Nucleus 5 Sound Processor in both fixed and adaptive speech in noise when presented directly in front. Significant improvements were observed for speech recognition in spatially-separated speech in noise (S0N180) with ForwardFocus enabled compared to the Nucleus 5 Sound Processor using Beam.



Mean and standard deviation scores for each test condition. The Fixed noise (a) test condition was used to evaluate the Nucleus® 7 Sound Processor with ForwardFocus (FF) enabled and adaptive noise (b) test condition was used to evaluate speech recognition. ** Represent statistically significant difference (p<0.05). Adapted from Goffi-Gomez et al. 2021.

By upgrading to the Nucleus® 7 Sound Processor, and enabling ForwardFocus, patients can improve their communication and connection to the world around them, particularly in noisy environments.



“Improvements can be seen after 3-4 years that you didn’t have from the beginning. So basically, you only have a positive trend in front of you. That’s amazing.”

Tina, Cochlear™ Nucleus® System recipient

Clinical evaluation of the Nucleus® 6 cochlear implant system: Performance improvements with SmartSound iQ.^{3,§}

Mauger SJ, Warren CD, Knight MR, et al.

Study design

Twenty-one Australian, post-lingually deafened implanted adults, ranging from 49 – 90 years, participated in a study comparing speech recognition with the Nucleus® 5 Sound Processor to the Nucleus 6 Sound Processor. Participants scored at least 30% on sentences at +15dB SNR using their Nucleus 5 Sound Processor. Cochlear implant listening experience ranged from 1 - 10 years.

Participants were tested in quiet at 50dB SPL with monosyllabic words and at 65dB SPL with an adaptive sentences-in-noise test, with the noise level adapted to determine the SRT for 50% correct scores. Speech-in-noise evaluations used speech-weighted noise and 4-talker babble in two spatial configurations, speech and noise from the front (SONO) and spatially separated (SON90,180,270). Participants received a Nucleus 6 Sound Processor and had at least two weeks of take-home use before the first test session.

Results

In quiet, group mean scores for speech recognition were equivalent between the two sound processors. In the 4-talker babble, spatially-separated noise condition, speech recognition was significantly better with the Nucleus 6 Sound Processor using SCAN[†], Beam[®] and zoom programs compared to the Nucleus 5 ‘Preferred’ program ($p < 0.001$). Speech recognition mean scores with the Nucleus 6 Sound Processor using no preprocessing (None) and ‘Standard’ programs were superior to the Nucleus 5 ‘Preferred’ program ($p < 0.001$). All individuals easily accepted the new default Nucleus 6 Sound Processor programs and settings.

Conclusion

The Nucleus 6 Sound Processor with SCAN demonstrated that automated scene classification can deliver improved hearing in simulated diverse listening environments. Speech recognition in noise improved significantly using the Nucleus 6 Sound Processor with SCAN compared to the Nucleus 5 Sound Processor. The Nucleus 6 Sound Processor with SCAN provided superior performance outcomes in noise compared to the Nucleus 6 Sound Processor programs which did not use SCAN.

Upgrading to newer sound processors can offer hearing performance improvements through automation advancements, such as SCAN, making it easier for patients to continue listening well as they move between different sound environments.

Benefits in noise from sound processor upgrade in thirty-three cochlear implant users for more than 20 years.⁴

Mosnier I, Sterkers O, Nguyen Y, et al.

Study design

In a French study, 33 adults implanted with a Nucleus® CI22M cochlear implant were evaluated to compare hearing benefits with the Nucleus® 6 Sound Processor to their own sound processor. Participants were long-term CI patients, with 21 years listening experience on average. Onset of deafness varied: 16 participants were prelingual and implanted between 3 – 16 years, two were perilingual and implanted at 37-38 years, and 15 were postlinguistically deafened and implanted between 16 – 60 years. Thirty-one participants used the Freedom® Sound Processor and two used the ESPrit™ 3G Sound Processor programmed with the SPEAK coding strategy. They were fitted with the Nucleus 6 Sound Processor with SCAN[†] and non-SCAN programs, the SPEAK coding strategy and the same program settings as in their legacy sound processor.

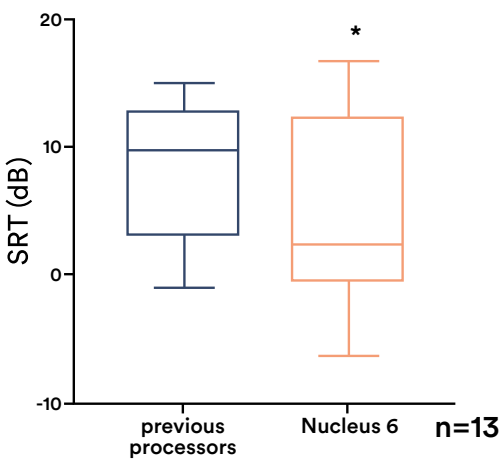
Results

Following two months of listening experience with the Nucleus 6 Sound Processor, 31/33 (94%) participants used the SCAN[†] programs daily. In quiet, median word and phoneme scores at 60dB SPL were similar between the Nucleus 6 Sound Processor and legacy sound processors. A subgroup of pre- and post-linguistically deafened participants were evaluated to determine the SRT in quiet (18/33) and noise (13/18). In quiet and noise, the median SRTs decreased significantly (i.e., hearing significantly improved in more difficult listening conditions), with the Nucleus 6 Sound Processor compared to their legacy sound processor ($p < 0.05$ and $p < 0.0005$, respectively).

Conclusion

Long-term CI patients implanted with the Nucleus CI22M implant who used earlier sound processors obtained significant hearing benefits, such as speech recognition in noise, when they upgraded to the Nucleus 6 Sound Processor. Most were able to adapt to using SCAN as their daily default once upgraded.

Speech recognition in noise for CI22M patients using the Nucleus® 6 Sound Processor



Distribution of group speech recognition outcomes for sentences in noise (dB SNR) for previous Nucleus sound processor (own) and the Nucleus 6 Sound Processor. The box plots show the first and third quartiles values and the central line the median value. Lower dB SNR values indicate better speech reception thresholds. * Indicates a significant difference at $p < 0.0005$. Adapted from Mosnier et al. 2020.

Even patients who received their implant over 20 years ago can achieve performance improvements today by upgrading their sound processor to access the latest sound processing technology.



Comparison of Speech Recognition in Cochlear Implant Users with Different Speech Processors.⁵

Pinheiro MMC, Mancini PC, Soares AD, et al.

Study design

In a Cochlear-sponsored, multi-center Brazilian study, 51 CI users were evaluated to compare speech recognition between their Nucleus® 5 Sound Processor and the off-the-ear Nucleus® Kanso® Sound Processor. Participants were post-lingually deafened, aged 13 years and older (mean = 35 years), with 5.8 years of CI listening experience, on average.

Each participant’s Nucleus 5 Sound Processor ‘Everyday’ program (using ADRO+ASC) was converted for the Kanso Sound Processor and SCAN[†] was activated in the Kanso Sound Processor. Immediately after fitting, participants were tested using the Nucleus 5 and Kanso Sound Processors in a randomized order. Individuals were evaluated with the Brazilian-Portuguese Hearing in Noise Test in quiet at 65dB SPL (S0) and in fixed noise (S0N0) at +10dB SNR to determine speech recognition percent correct scores. Tests in noise (S0N0) were performed in an adaptive SNR to determine the SRT for 50% correct scores. Speech and noise were presented from one frontal loudspeaker (S0N0). Order effects of sound processor assessment were accounted for in the data analysis.

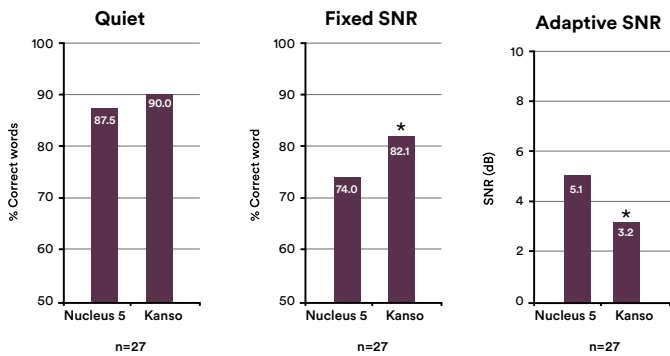
Results

In quiet, group mean speech recognition was similar between the Nucleus 5 and Kanso Sound Processors. In noise, at a fixed SNR, speech recognition with the Kanso Sound Processor was significantly better than with the Nucleus 5 Sound Processor ($p < 0.05$). In noise with an adaptive SNR, the mean SRT was significantly lower (i.e., better hearing in more challenging listening conditions), with the Kanso Sound Processor than the Nucleus 5 Sound Processor ($p < 0.05$).

Conclusion

Speech recognition and SRT in noise were significantly better using the Kanso Sound Processor with SCAN compared to the Nucleus 5 Sound Processor with ADRO and ASC.

Speech recognition in quiet and in noise conditions with the Nucleus® 5 and Kanso® Sound Processors



Mean speech recognition scores for sentences in quiet (a) and in two noise conditions, fixed (b) and adaptive (c), comparing the Nucleus 5 Sound Processor to the Nucleus Kanso Sound Processor in the unilateral condition. * Represents significant difference ($p < 0.05$). Adapted from Pinheiro et al. 2021.

The off-the-ear Nucleus® Kanso® Sound Processor provides hearing benefits in noise over older generation behind-the-ear sound processors. Patients considering an upgrade now have a choice of wearing options.



New sound processor technology helps improve patient hearing outcomes.⁶

Plasmans A, Rushbrooke E, Moran M, et al.

Study design

In a multi-center study, 25 experienced pediatric CI users from Belgium, Australia and New Zealand were evaluated to compare the benefits of the Nucleus® 6 Sound Processor with their Nucleus® 5 Sound Processor. Children were aged between 6-15 years at the time of testing and had an average 6.1 years of CI experience.

This study aimed to determine if speech recognition improved when using the default automated scene classification program SCAN and noise reduction technologies, SNR-NR and WNR[†], in the Nucleus 6 Sound Processor compared to their Nucleus 5 Sound Processor.

All children were tested in quiet using monosyllabic words at 60dB SPL and in noise using monosyllabic words (Dutch-speaking) or sentences-in-noise (English-speaking) during three test sessions, about two weeks apart. Speech in noise was presented from one frontal loudspeaker (S0N0) with speech at 65dB SPL and speech-weighted noise at a fixed level. Speech in noise outcomes were analyzed separately by language.

Results

In quiet, monosyllabic word recognition was equivalent between the Nucleus 5 Sound Processor and Nucleus 6 Sound Processor, irrespective of language. Speech recognition in noise indicated similar performance between the Nucleus 5 Sound Processor-preferred and Nucleus 6 Sound Processor-custom programs for each group. Speech recognition scores were significantly better with SCAN on the Nucleus 6 Sound Processor compared to the Nucleus 5 Sound Processor preferred program ($p < 0.05$, English speakers and $p < 0.01$, Dutch speakers).

Conclusion

Mean speech recognition scores in noise (on both words and sentences) were significantly better with the Nucleus 6 Sound Processor SCAN program compared to the Nucleus 5 Sound Processor preferred program. Using SCAN, especially in background noise, provided speech recognition benefits in children upgrading from their older sound processor. All children easily accepted the Nucleus 6 Sound Processor.

Cochlear™ Nucleus® sound processors provide children with the latest SCAN technology, helping them hear their best by automatically adapting to different environments.

CI = cochlear implant; SPL = sound pressure level; SRT = speech reception threshold

Cochlear sponsored study; Refer to Appendix for full description of all sound processing technologies. CI = cochlear implant; SNR-NR = signal-to-noise ratio – noise reduction; WNR = wind noise reduction; SPL = sound pressure level

“Every time Cochlear updates a sound processor, the experience is dramatically enhanced... I can hear more clearly and well, with less effort (and) without a doubt, my quality of life improves.”

Jack, Cochlear™ Nucleus® System recipient



Impact of new sound processor technology on patient satisfaction

Seeing the positive impact improvements in hearing outcomes have made to your patients' quality of life can also provide you, their hearing health professional, with a sense of reward and enjoyment.⁷⁻¹⁰

Regardless of when they were first implanted, patients of all ages report the difference a new sound processor has made to their everyday experience of life.⁷⁻¹⁰

The studies summarized in the following section include patient reported hearing benefits using a variety of established self-report scales. They examine the overall well-being of participants in several health-domains including daily hearing function and its impact on everyday life.⁷⁻¹⁰

Upgrade to Nucleus® 6 in previous generation Cochlear™ sound processor patients.⁷

Biever A, Gilden J, Zwolan T, et al.

Study design

In a US multi-center clinical study series (3 separate studies at different sites with a range of implant types and sound processors), 80 post-linguistically deafened participants, ranging from 13 – 93 years, were evaluated to compare speech recognition, usability and satisfaction outcomes with the Nucleus® 6 Sound Processor to these older sound processors: Nucleus® 5 Sound Processor (n = 40); Freedom® Sound Processor (n = 25); and Freedom or ESPrit™ 3G Sound Processors (n = 15).

Participants were evaluated with their processor and preferred program and with the Nucleus 6 Sound Processor with preprocessing technologies SCAN, SNR-NR and WNR[†]. Participants were assessed with monosyllabic words in quiet (S0) and with sentences in noise at +5dB SNR or +10dB SNR (SON90 or 270). After the take-home experience (1 or 3 months), quality of hearing and device usability was evaluated using the SSQ-C and a customized version of DUQ.

Results

Speech recognition in quiet was equivalent between the Nucleus 6 Sound Processor and the participants’ own processor, except for a small but significant improvement (p = 0.027) with the Nucleus 6 Sound Processor over the Freedom Sound Processor. Compared to their sound processor, speech recognition in noise improved significantly with the Nucleus 6 Sound Processor for 89% (71/80) of participants (p < 0.0001 Study 1, p < 0.001 Study 2, p = 0.002 Study 3).

Most participants reported better hearing ability for daily listening with the Nucleus 6 Sound Processor than with their current sound processor on SSQ-C subscales: 91% (73/80) Speech Hearing; 81% (65/80) Spatial Hearing; and 95% (76/80) Qualities of Hearing. Most participants reported overall satisfaction and preference for sound quality with the Nucleus 6 Sound Processor compared to their sound processor via the DUQ, with 91% (73/80) expressing preference and overall satisfaction, and 99% (79/80) indicating they would likely recommend it to someone else.

Conclusion

The Nucleus 6 Sound Processor, with signal processing technologies designed to improve speech recognition in difficult listening environments, provided significant benefits compared to older sound processors. Benefits for hearing ability in everyday listening situations were reported subjectively and demonstrated clinically for speech recognition in noise for most participants.

Most patients who have upgraded to the latest sound processors are likely to prefer, and gain significant benefit from, the newer sound processor technology and experience improvements in overall satisfaction with everyday life.

Cochlear-sponsored study. SNR-NR = signal-to-noise ratio – noise reduction; WNR = wind noise reduction; SSQ-C = Speech, Spatial and Qualities of Hearing Scale – Comparative version; DUQ = device use questionnaire

Clinical outcomes with the Kanso off-the-ear cochlear implant sound processor.⁸

Mauger SJ, Jones M, Nel E, Del Dot J.

Study design

In an Australian study, 20 post-lingually deafened implanted adults, ranging in age from 30 – 85 years, were evaluated to compare performance and wearer preference with the off-the-ear (OTE) Nucleus® Kanso® Sound Processor and the behind-the-ear (BTE) Nucleus® 6 Sound Processor. Both use dual-microphone technology and adaptive directional programs. Inclusion criteria of at least 6-months experience with the Nucleus® 5 Sound Processor or the Nucleus 6 Sound Processor and scores of 30% or more on sentences in noise was required to participate.

After a two-week take-home trial with the Kanso Sound Processor, performance and preference was assessed and compared with a newly fitted Nucleus 6 Sound Processor. Speech recognition assessments were performed in quiet and in fixed noise using one frontal speaker (S0, SON0), and in dynamic spatially-separated speech in noise (SONrear-hemi). At study end, participants completed a survey, rating their hearing ability and personal preference comparing the Kanso Sound Processor to their current sound processor.

Results

Group mean scores for speech recognition in quiet and in fixed noise from in front were equivalent between the Kanso Sound Processor and Nucleus 6 Sound Processor, using a standard program. In dynamic noise (SONrear-hemi), both sound processors using directional technology, provided significant advantages over the standard program (p < 0.001). The mean SNR was significantly lower (i.e., better hearing in more difficult listening conditions), for the speech reception threshold (SRT50%) with the Nucleus 6 Sound Processor (p < 0.001).

The OTE sound processors may be an option for individuals who desire greater comfort and simplicity over a BTE sound processor, without compromising hearing performance.

Cochlear-internal study. OTE = off-the-ear; BTE = behind-the-ear; SNR = signal-to-noise ratio; SRT = speech reception threshold

When comparing their own sound processor to the Kanso Sound Processor, Figure 1 shows participant survey ratings for the Kanso Sound Processor were significantly more favorable.

Survey responses: Comparative User Ratings for the OTE Kanso® Sound Processor versus their own BTE sound processor

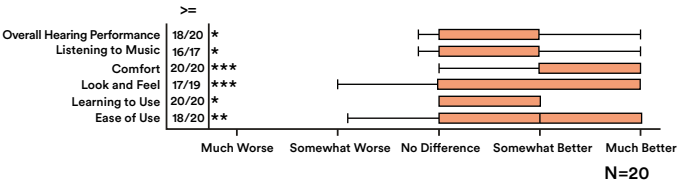


Figure 1: A subset of survey responses for the group showing comparative ratings for the Kanso Sound Processor compared to their own sound processor. The domains rated are shown on the left. The proportion of 20 subjects rating the Kanso Sound Processor as equal to (=) or better than (>) than their own sound processor is shown next to each domain. The distribution of ratings across each response category from “Much Worse” to “Much Better” is shown by box plots for the 25th, 50th and 75th percentiles. Error bars show the 5th and 95th percentiles. Significant difference in group ratings compared to “No Difference” is indicated by * p<0.05, ** p<0.01, and *** p<0.001 for each domain. Adapted from Mauger et al. 2017.

Conclusion

Participants rated the Kanso Sound Processor significantly higher compared to their current processor for daily hearing and usability. The Kanso Sound Processor provided similar hearing performance to the Nucleus 6 Sound Processor for speech in quiet and noise from the front.

Benefits from upgrade to the CP810 sound processor for Nucleus® 24 cochlear implant patients.⁹

Mosnier I, Marx M, Venail F, et al.

Study design

In a French, multi-center study, 35 implanted adults, ranging from 12 – 79 years, using a Cochlear™ Nucleus® CI24 Cochlear Implant, were evaluated to compare speech recognition with the Nucleus® 5 Sound Processor to their current legacy sound processors. Most participants (n=22) used a Nucleus® ESPrit™ 3G Sound Processor, with the remaining 13 using a Nucleus® Freedom™ Sound Processor. Participants had a minimum of four years listening experience with their current sound processor and scored at least 10% on monosyllabic words or 20% on disyllabic words at 65dB SPL. Speech recognition in quiet and noise was assessed, and the APHAB questionnaire was completed.

At baseline, participants received a new legacy sound processor with their ‘Everyday’ program loaded. In quiet, monosyllabic words were tested at 50 and 60dB SPL from one frontal loudspeaker (S0). Sentences in spatially-separated speech in noise were presented at 65dB SPL from the front in cocktail party noise (S0N90,180,270), to determine the SNR for the speech reception threshold (SRT50%). Participants were upgraded to the Nucleus 5 Sound Processor with their previous ‘Everyday’ program and a new ‘Noise’ program including ADRO, Autosensitivity and zoom. After a few months of take-home experience, speech recognition was reassessed with the Nucleus 5 Sound Processor and the APHAB was completed.

Results

Group mean word scores in quiet were significantly higher with the Nucleus 5 Sound Processor compared to legacy sound processors at 50dB and 60dB SPL (p <0.0001, p <0.001, respectively). Speech recognition in noise with the Nucleus 5 Sound Processor ‘Noise’ program was significantly better compared to their older sound processors (p < 0.0001).

Twenty-seven participants completed the APHAB. Mean global and subscale scores indicated hearing difficulties were experienced significantly less of the time with the Nucleus 5 Sound Processor compared to their legacy sound processors (p < 0.001).

Conclusion

Outcomes for long-term Nucleus CI24 implant patients upgrading to the Nucleus 5 Sound Processor showed clear benefits for speech recognition in quiet and noise and for real-world listening compared to legacy sound processors.

Long term users of Nucleus® sound processors experienced less hearing difficulties following an upgrade to newer sound processor technology, which helps provide patients with confidence to engage with the world around them.

CI = cochlear implant; SPL = sound pressure level; SNR = signal-to-noise ratio; APHAB = Abbreviated Profile of Hearing Aid Benefit; EC=ease of communication, BN=background noise, RV= Reverberation, AV=Aversiveness.

Controlled comparative clinical trial of hearing benefit outcomes for users of the Cochlear™ Nucleus® 7 Sound Processor with mobile connectivity.¹⁰

Warren CD, Nel E, Boyd PJ.

Study design

In an Australian study, 37 post-linguistically deafened implanted adults, ranging from 25 – 81 years, were evaluated to compare the Nucleus® 7 Sound Processor with their Nucleus® 5 Sound Processor or Nucleus® 6 Sound Processor. Participants were from multiple centers across Australia and scored at least 30% on sentences at +15dB SNR with their processor.

At baseline, participants were fitted with the Nucleus 7 Sound Processor using the same parameter settings as their current sound processor, and they participated in a three-month take-home trial. Evaluations were performed at baseline and again after three months. A subset of 24 participants were evaluated with the new processor and their current sound processor using speech recognition measures in quiet (S0), in fixed noise (S0N0) and in spatially-separated speech in noise (S0N90,180,270). Evaluation of benefits and satisfaction between sound processors included the subjective COSI and customized PCQ.

Participants rated change in hearing ability in self-selected listening situations using the COSI from ‘much better’ to ‘much worse’. Using the PCQ, participants rated five questions regarding general hearing performance, phone communication and enjoyment of music to determine sound processor preference on a scale from 0 to 100 with > 50 indicating preference for the Nucleus 7 Sound Processor.

Results

The COSI was completed with 92% (34/37) participants. Benefit ratings were significantly higher for the Nucleus 7 Sound Processor compared to the legacy sound processors for ‘hearing on the telephone’, ‘conversation

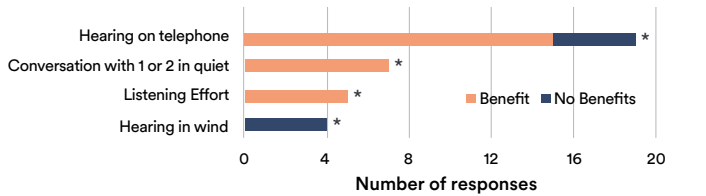
in quiet’ and ‘listening effort’ (p < 0.05). The PCQ was completed by 95% (35/37) participants, and mean ratings indicated significantly better hearing with the Nucleus 7 Sound Processor compared to older sound processors (p < 0.05).

In quiet, speech recognition was equivalent between the three sound processors. In noise, the Nucleus 7 Sound Processor provided significant speech recognition benefits compared to the Nucleus 5 Sound Processor (p < 0.05) and equivalence when compared to the Nucleus 6 Sound Processor.

Conclusion

Most participants expressed high satisfaction and hearing benefits with the Nucleus 7 Sound Processor compared to their current sound processor, particularly when listening on the telephone, in quiet and in noise. Participants also rated usability and comfort more highly for the Nucleus 7 Sound Processor.

Subjective reports of listening benefits with the Nucleus® 7 Sound Processor compared to their own sound processor.



Subjective responses showing a subset of categories of goals self-selected by the study group (via the COSI) to compare hearing benefits with the Nucleus 7 Sound Processor to their own sound processor. Horizontal bars show the number of subjects selecting each goal, and the proportion who reported benefit or no benefit for each. Significant differences in reported benefit perceived with the Nucleus 7 Sound processor is indicated by * p<0.05. Adapted from Warren, et al. 2019.

Mobile connectivity†, usability and comfort available in the Nucleus® sound processors may improve recipient satisfaction across multiple listening situations and perceived listening effort.

Cochlear-sponsored study. SNR = signal-to-noise ratio; COSI = Client-Orientated Scale of Improvement; PCQ = Processor Comparison Questionnaire

“Being able to take a test* of the same quality as the one I would take at the clinic means a lot more freedom. I’m able to make better use of my time and money. I can focus on what I like doing—having fun instead of driving to and from the hearing clinic.”

Stefan, Cochlear™ Nucleus® System recipient



*Cochlear™ Remote Check††



Supporting patient-centered care with Remote Care technologies

Using Remote Care technologies, hearing health professionals can supplement in-clinic visits by offering quality care to patients from the comfort of their own home. Patients in the latest sound processor technology can receive timely care without taking time off work or incurring travel expenses to visit the clinic. Remote Care can help enable clinic efficiencies by allowing you to prioritize in-clinic visits for patients requiring more comprehensive care and see new patients to help more people hear their best.¹¹⁻¹²

Clinicians can more easily access accurate data about how patients are using their device/s in their everyday lives—which can lead to more efficient and personalized care.

The studies summarized on the following pages show how remote care tools, available in next-generation sound processors, enable clinicians to stay connected to their patients and provide timely care virtually, without a clinic visit.¹¹⁻¹²

Remote Check^{††} test battery for cochlear implant patients: proof of concept study.¹¹

Maruthurkkara S, Allen A, Cullington H, et al.

Study design

This proof-of-concept multi-center trial in the United Kingdom and Australia involved 93 CI patients, (73 adults and 20 children), ranging from 6 – 87 years, who were all Nucleus[®] 7 Sound Processor users. There were 28 clinicians across 4 sites. The study aims included assessment of whether Remote Check was an acceptable tool for patient use, and whether it provided sufficient clinical information to determine if an in-clinic visit was required.

Prior to their face-to-face appointment, participants or parent/caregivers completed the Remote Check test battery in the clinic. The test battery included automated measures and patient-driven tasks. Clinicians then examined the test battery results and noted where an in-clinic visit was required. The clinical appointment followed, including identification of issues requiring follow-up. The issues detected by the test battery and the face-to-face clinical visit were then compared.

Results

Remote Check identified several patient and device issues requiring clinical follow up. The Remote Check Speech in Noise test (a digit triplet test or DTT) was completed by 96% (89/93) patients. Self-administered aided hearing thresholds were considered reliable in 96% (89/93) of patients. There was 99% (92/93) agreement between methods regarding recommendations for participants requiring follow-up. The majority, 77% (72/93) of patients or parents/caregivers said they would be satisfied or very satisfied if a clinic visit was based on a clinician’s review of Remote Check test battery results (p < 0.001).

Conclusion

This Remote Check test battery is the first comprehensive self-monitoring tool designed for use by CI patients outside of the clinic. It informs clinicians about possible issues that might need further clinical intervention for patient management and was considered acceptable by most participants. Patients and parents/caregivers expressed a high level of satisfaction with remote monitoring as a care option.

The latest generation of Cochlear[™] sound processors enable clinicians to monitor their patients remotely and help deliver quality care, and a high level of satisfaction, without the need for a clinic visit.

Cochlear-sponsored study. CI = cochlear implant; DTT = digit triplet test

Evaluation of Remote Check^{††}: A clinical tool for asynchronous monitoring and triage of cochlear implant patients.¹²

Maruthurkkara S, Case S, Rottier R.

Study design

In an Australian study, 32 cochlear implant (CI) patients, (28 adults and 4 children), ranging from 7 – 86 years, assessed the Remote Check App. The aim was to assess: 1) ease of use, 2) acceptance for at-home use, 3) test-retest reliability, 4) comparison of recipient self-testing to clinicians’ evaluations. The Remote Check test battery included implant site photographs, streamed digit triplet test (DTT), streamed aided threshold test (ATT), a patient questionnaire, and automated impedance check, device-use data and diagnostics.

Participants performed self-testing at home and in the clinic, using their preferred program. Participants completed self-administered DTT and ATT. Self-administered ATTs were compared to routine clinical audiometry in the free-field. Following the clinic evaluation, participants re-administered the self-tests at home. Participant feedback on ease of use and information related to in-clinic appointments was then assessed.

Results

ATT and DTT outcomes between self-administered, clinic and at-home evaluations were equivalent. The test–retest difference for streamed, self-administered DTT versus free-field results was acceptably small (< 2dB). Self-administered, streamed ATT showed significantly lower (i.e., better hearing) aided thresholds compared to clinician-measured thresholds (p < 0.001). Most participants (87%) rated Remote Check as easy/very easy to use (p < 0.001). Most participants (89%) were satisfied/very satisfied with Remote Check (p < 0.001), and 82% agreed “Remote Check is more convenient than in-clinic monitoring” (p < .001). Many participants (77%) indicated they would likely use the app in the future (p = 0.01).

Conclusion

Most participants found Remote Check an easy to use, convenient option to consider in their hearing healthcare. With access to remotely recorded results, clinicians can monitor their patient’s progress and complement routine patient management and decisions. Remote monitoring has the potential to reduce unnecessary clinic visits, patient travel time and expenses.

Remote Care tools included in the latest generation of Cochlear[™] sound processors may increase clinic efficiency whilst reducing patient costs.

Cochlear-sponsored study. CI = cochlear implant; DTT = digit triplet test; ATT = aided threshold test



“It’s a huge difference. Even the ones that were doing really well with their processors, they get the upgrade, and they’re doing even better.”

Audiologist, USA



The health economic benefits of cochlear implants, including upgrades

Cochlear implant (CI) treatment, including regular sound processor upgrades, has been shown to be cost-effective and beneficial to both patients and society.¹³⁻¹⁶ The improved durability of next-generation sound processors reduces the need for replacement processors and parts, and maintenance. Together with rechargeable battery options, upgrades from older devices provide both cost efficiencies and environmental benefits.¹³⁻¹⁶

The studies summarized in the following section demonstrate savings for patients, professionals and health systems. As sound processor technology and programming software evolve, more efficient and quicker fitting times could bring additional efficiencies that may further reduce overall CI treatment costs.¹³⁻¹⁶

Cost-benefit Analysis of Cochlear Implants: A Societal Perspective.¹³

Neve OM, Boerman JA, van den Hout WB, et al.

Study design

In a Dutch study, a CI cost-benefit analysis was conducted across three groups of CI-patients: (1) prelingually deafened children implanted bilaterally simultaneously by age 1-year; (2), working-age adults implanted unilaterally by age 40-years; and (3) retired seniors implanted unilaterally by age 70-years. The adult participants had progressive, profound hearing loss and used a contralateral HA as standard practice in the Netherlands. Controls for each group included similar individuals with bilateral HAs under regular care.

The costs and benefits were estimated over the expected lifetime for each group. The model incorporated diagnosis treatment combinations for initial implantation, for external sound processor replacement every 5 years, and for CI aftercare every 3-years. Health outcomes and cost were compared between the treatment and control groups. QALYs, expressed monetarily, were counted as treatment-benefit. Cost analysis determined the incremental treatment costs. The model contained three types of societal costs of patients and informal caregivers, namely: healthcare, educational, and productivity.

Note: Net benefit was calculated by subtracting the sum of all costs from the sum of all benefits to assess whether benefits exceeded costs of the intervention.

Results

Children in group 1 had a lifetime positive net benefit of €433,000, indicating simultaneous bilateral CI is more effective and less costly than no CI. Analysis indicated that societal costs for bilateral CI in children were below the willingness-to-pay threshold of €50,000/QALY. A reduction in their educational costs of approximately €118,000 was also demonstrated.

Adults in groups 2 and 3 had a total net benefit of €275,000 and €76,000, respectively indicating unilateral CI is cost effective. Analysis demonstrated that gain in health-related quality of life was the most important factor influencing net benefit.

Total CI benefits exceeded the total cost in all three groups.

Conclusion

This study demonstrated CI treatment including processor replacement once every 5 years provided clear societal and patient benefits for all three groups. Simultaneous bilateral implantation can reduce educational costs for children compared to no implantation. Earlier treatment in a CI candidate's working lifetime may lead to higher societal benefits than treatment later in life.

Currency Exchange

Euro	USD	CAD
€ 433,000	\$ 463,310	\$ 593,210
€ 50,000	\$ 53,500	\$ 68,500
€ 275,000	\$ 294,250	\$ 376,750
€ 76,000	\$ 81,320	\$ 104,120

as of May 25, 2022

Cochlear implant treatment, including regular sound processor upgrades, has been shown to be economically beneficial to patients and society.

Cost–Utility Analysis of Cochlear Implantation in Australian Adults.¹⁴

Foteff C, Kennedy S, Milton A, et al.

Study design

This Australian study evaluated the cost–utility of bilateral HAs compared with unilateral, sequential, and simultaneous bilateral CIs in adults with bilateral severe-to-profound SNHL.

The cost–utility analysis used Australian healthcare data to identify the proportion of adults transitioning from bilateral HAs to each CI health state: unilateral, sequential bilateral, and simultaneous bilateral implant. The model followed a Markov process, allocating costs and utility to time spent in each 1-year cycle; costs and outcomes were discounted at 5% annually for a base case analysis from a national health system perspective.

The main outcome was incremental costs per QALY. Costs related to surgery, audiology and rehabilitation were included in the analysis, while costs borne by patients were excluded. Costs were evaluated over a lifetime with sound processor replacements occurring every 5 years.

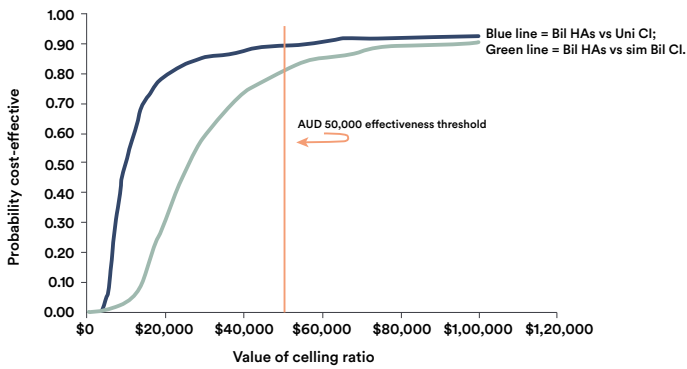
Results

When compared with bilateral HAs the incremental cost–utility ratio for the CI-treatment population was AUD11,160 per QALY gained. This ratio included the weighted mean costs of adults treated with each CI health state. When a cost-effectiveness threshold of AUD50,000/QALY was applied, results confirmed the weighted CI-treatment regime was cost-effective when compared with bilateral HAs.

Conclusion

This study demonstrated all three CI health states, unilateral, sequential bilateral and simultaneous bilateral CI, as cost-effective compared to bilateral hearing aid usage in adults.

Cost-effectiveness acceptability curves over time



Cost-effectiveness acceptability curves for unilateral CI vs bilateral HAs (blue line) and for simultaneous bilateral CI versus bilateral HAs (green line) with an AUD50,000 effectiveness threshold. CI = cochlear implantation; HA = hearing aids. Adapted from Foteff, et al. 2016.

Currency Exchange

AUD	USD	CAD
\$ 11,160	\$ 7,924	\$ 10,156
\$ 50,000	\$ 35,500	\$ 45,500

as of May 25, 2022

The research proposes that as sound processor technologies and programming software evolve, more efficient and shorter fitting times may bring additional cost efficiencies that further reduce overall cochlear implant treatment costs.

The cost-effectiveness of unilateral cochlear implants in UK adults.¹⁵

Cutler H, Gumbie M, Olin E, et al.

Study design

This UK study aimed to estimate the cost-effectiveness of unilateral CI in adults with severe-to-profound HL under the NHS. Adults who wore a HA receiving some benefit and adults with no HA were included.

Investigators captured a lifetime of benefits and cost differences associated with a unilateral CI from an NHS perspective. They developed a clinical pathway to estimate resource use and changes in the last two decades. NHS data was used to determine unit cost changes to indicate changes in the price of unilateral CI. The model included device upgrades and device replacements and health-related quality of life benefits (to determine quality adjusted life years [QALY]).

Results

The study showed that for an adult who had worn a HA and received a CI in the same ear, an average incremental lifetime cost increase of £37,988 and additional 3.18 QALYs was observed. This resulted in an incremental cost-effectiveness ratio (ICER) of £11,946 per QALY gained. For an adult who did not use a HA in the implanted ear, there was an average incremental lifetime cost increase of £38,449 and an additional 3.66 QALYs observed. This resulted in an ICER of £10,499 per QALY gained.

Conclusion

These study results suggest unilateral CI for adults in the UK with severe-to-profound HL is cost-effective when compared to either a HA or no HA, improving quality of life and overall social welfare. CI treatment remained cost effective over time despite changes in clinical practice and increased healthcare costs.

Currency Exchange

£	USD	CAD
£ 37,988	\$ 47,792	\$ 61,257
£ 11,946	\$ 15,029	\$ 19,263
£ 38,449	\$ 48,372	\$ 62,000
£ 10,499	\$ 13,208	\$ 16,930

as of May 25, 2022

Improved quality of life and societal welfare benefits for adults with severe-to-profound hearing loss could be achieved through increasing access to, and awareness of, the potential benefits from cochlear implants, including regular external device upgrades.

Cochlear-internal study. UK = United Kingdom; CI = cochlear implant; HL = hearing loss; NHS = National Health Service; HA = hearing aid; QALY = Quality-adjusted life year; ICER = incremental cost-effectiveness ratio

The cost-effectiveness of Cochlear implants in Swedish adults.¹⁶

Gumbie M, Olin E, Parkinson B, et al.

Study design

This Swedish study estimated the cost-effectiveness of unilateral CI compared to a HA for adults aged 19 years and older, with severe-to-profound SNHL and who wore a HA and obtained some benefit before implant.

The model compared a unilateral CI to a HA and included sound processor upgrades every 8.83 years. Health outcomes were reported in QALYs. The ICER was estimated and a cost-effectiveness threshold of SEK 250,000 per QALY gained was applied. A clinical pathway was developed in consultation with clinical experts at two large Swedish CI centers. Future costs and health outcomes were discounted at 3% per annum. No direct or indirect costs borne by the patient were included in the model.

Results

The study showed that for an adult with severe-to-profound SNHL who received a unilateral CI, compared to a HA providing some benefit, health costs increased by SEK 435,147 and health-related quality of life increased on average by 3.10 QALYs. This analysis equated to an ICER of SEK 140,474 per QALY gained.

The study conducted analysis for three additional scenarios: 1) patients below 50 years of age (from 61 years); 2) sound processor upgrades every 5 years (from every 8.83 years); and 3) an increased proportion of eligible CI candidates to 70% (from 56%). Analysis showed that these scenarios decreased the estimated ICER associated with a unilateral CI to SEK 138,751 per QALY gained. Such scenarios led to an estimated 92% likelihood of unilateral CI being cost-effective compared to using a HA.

Conclusion

The study found that in Sweden, earlier treatment for adults with a unilateral implant in eligible CI candidates could improve cost-effectiveness compared to delayed CI treatment for adults.

Currency Exchange

SEK	USD	CAD
250,000	\$ 25,329	\$ 32,467
435,147	\$ 44,089	\$ 56,519
140,474	\$ 142,35	\$ 18,246
138,751	\$ 14,061	\$ 18,025

as of May 25, 2022

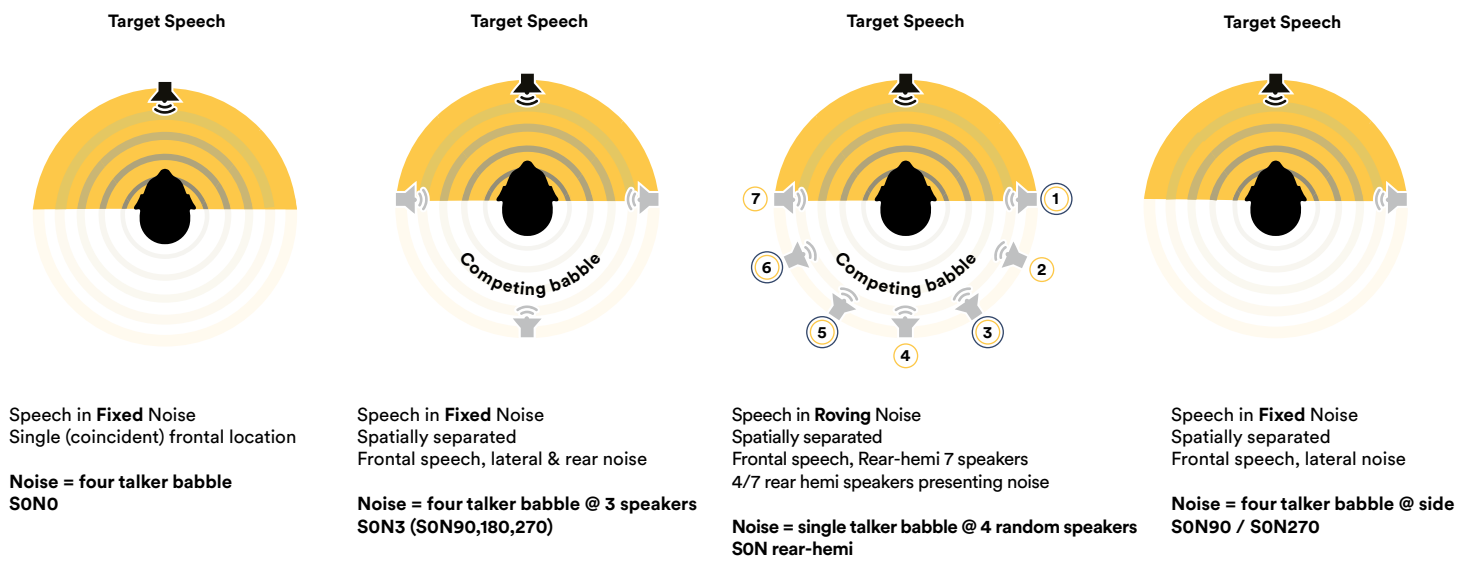
Earlier implantation of a unilateral cochlear implant, with a reduction in the upgrade cycle from nine years to five years, is proven to be cost-effective.

CI = cochlear implant; HA = hearing aid; SNHL = sensorineural hearing loss; QALY = Quality-adjusted life year; ICER = incremental cost-effectiveness ratio; SEK = Swedish Krona

a. Speaker set ups for clinical tests of speech recognition in noise.

These diagrams aim to demonstrate the different speaker set ups typically used to clinically assess speech recognition performance in noise. All have been referenced in one or more summaries included in this document. It is important to remember that performance may vary according to the speaker set up and *test condition variables, making direct comparisons between different methods invalid.

*Note: Many other variations in test conditions may influence hearing performance such as: presentation levels of speech and noise, speech materials, noise types, fixed or dynamic conditions, and the speech processing technologies in use.



b. Cochlear™ sound processing technology over the years

Cochlear has delivered incremental sound processing technology over the years, designed to help cochlear implant patients hear and understand in challenging everyday environments. The table and glossary below show the SmartSound® iQ^s input processing features introduced in each generation of Cochlear’s sound processors.

Signal processing comparison table							
	ESPrit™ 3G	Freedom	Nucleus 5	Nucleus 6	Kanso	Nucleus 7	Kanso 2
AGC	✓	✓	✓	✓	✓	✓	✓
Whisper™	✓	✓	✓	✓	✓	✓	✓
ADRO		✓	✓	✓	✓	✓	✓
ASC		✓	✓	✓	✓	✓	✓
Beam®		✓	✓	✓	✓	✓	✓
Zoom			✓	✓	✓	✓	✓
SNR-NR†				✓	✓	✓	✓
WNR‡				✓	✓	✓	✓
SCAN automation†				✓	✓	✓	✓
ForwardFocus#						✓	✓

SmartSound® iQ input processing definitions.

- **ADRO – Adaptive Dynamic Range Optimization**
A pre-processing algorithm which improves audibility of soft sounds and reduces the gain of loud sounds to optimize the comfort of the signal within the recipient’s dynamic range
- **AGC – Automatic Gain Control**
A front-end amplifier that applies fast-acting compression to reduce the gain of loud sounds to avoid distortion or peak clipping
- **ASC - Automatic Sensitivity Control (Autosensitivity)**
Provides dynamic adjustment of microphone sensitivity based on the noise floor of the incoming acoustic signal to reduce the negative effects of background noise
- **Beam® (adaptive directionality)**
A beamforming algorithm that adaptively adjusts microphone directionality according to the type and location of noise originating from behind and to the sides of the listener, making it easier to hear sounds from the front
- **ForwardFocus**
A user-controlled (manual) noise reduction feature designed to help listeners hear forward facing conversations in challenging listening environments by reducing multiple noise sources from behind them
- **SCAN**
An acoustic scene classifier which enables the optimal pre-processing and microphone directionality settings to be automatically applied for a given listening environment
- **SNR-NR – Signal-to-noise ratio-noise reduction**
An algorithm which reduces gain in frequency channels with poor signal-to-noise ratios to improve speech understanding in steady-state or constant background noise
- **Whisper™**
A fast-acting compression circuit that makes soft sounds easier to hear by compressing the more intense portions of the input signal
- **WNR – Wind noise reduction**
An algorithm which improves comfort in windy conditions by switching microphone directionality and reducing the gain in the frequency channels dominated by wind noise
- **Zoom (fixed directionality)**
A noise reduction algorithm which applies a fixed pattern of microphone directionality to provide maximum attenuation of a stationary noise source behind a listener

c. Abbreviations

- APHAB = Abbreviated Profile of Hearing Aid Benefit
ATT = aided threshold test
AUD = Australian Dollars
AV = Aversiveness
BN = background noise
CI = cochlear implant
COSI = Client-Orientated Scale of Improvement
DTT = digit triplet test
DUQ = device use questionnaire
EC = ease of communication
FF = ForwardFocus
HA = hearing aid
HL = hearing loss
ICER = incremental cost-effectiveness ratio
NHS = National Health Service
PCQ = Processor Comparison Questionnaire
QALY = Quality-adjusted life year
RV = Reverberation
SEK = Swedish Krona
SNHL = sensorineural hearing loss
SNR = signal-to-noise ratio
SNR50% = signal-to-noise ratio at 50% correct speech recognition scores
SNR-NR = signal-to-noise ratio – noise reduction
SPL = sound pressure level
SRT = speech reception threshold
SSQ-C = Speech, Spatial and Qualities of Hearing Scale – Comparative version
WNR = wind noise reduction

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 650,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

That's why more people choose Cochlear than any other hearing implant company.

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Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

Views expressed are those of the individual. Consult your health professional to determine if you are a candidate for Cochlear technology.

#ForwardFocus can only be enabled by a hearing implant specialist. It should only be activated 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.

† The Cochlear Kanso 2 Sound Processor is compatible with Apple and Android devices, for compatibility information visit www.cochlear.com/compatibility. The Cochlear Nucleus 7 Sound Processor is compatible with Apple and Android devices. For compatibility information visit www.cochlear.com/compatibility. The Cochlear Nucleus Smart App is available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.

‡SNR-NR, WNR and SCAN are approved for use with any recipient ages 6 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.

##Remote Check is intended for ages 6 and older. The Remote Check feature is only visible and accessible if the feature is enabled by a clinician. Clinicians should consider the suitability of the feature before enabling Remote Check. Remote Check does not replace clinical care and does not involve remote programming of the sound processor.

§It is recommended that SNR-NR, WNR, and SCAN be made available to any recipient, ages 6 and older, who is able to 1) complete objective speech perception testing in quiet and noise in order to determine and document performance and 2) report a preference for different program settings.

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