MASTER

Parametric self-fitting of cochlear implant systems at home

Roos, R.D.

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2004

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Parametric Self-Fitting of Cochlear Implant Systems at Home

by R.D. Roos

Master of Science thesis

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The Department of Electrical Engineering of the Eindhoven University of Technology accepts no responsibility for the contents of M.Sc. theses or practical training reports
Within a bony labrinthean cave, Reached by the pulse of the aerial wave, This sibyl, sweet, and Mystic Sens is found, Muse, that presides o'er all the Powers of Sound.

*Abraham Coles – Man, the Microcosm; and the Cosmos*
Preface

This is the report of my Master thesis that extended over the previous 16 months. Although the majority of the work was performed during the first 10 months, 6 additional months were needed to gather all the clinical data. During that time, this report was written. It marks the end of my period as a student of the Faculty of Electrical Engineering at the Eindhoven University of Technology. I enjoyed the help of numerous people, some of which I would like to thank at this point.

First of all, I would like to pay an enormous tribute to my mentor at Cochlear, Dr. Bas van Dijk, who has truly been a fantastic coach throughout the entire project. Without his enthusiasm and support, I would never have been able to successfully complete, let alone participate in this daring project, which is something I will never forget.

I would also like to give a great amount of thanks to Dr. Ir. L.L.M. Vogten, my mentor at the university who helped me greatly in putting this report together.

My colleagues at Cochlear, who were all extremely helpful. Special thanks at this point go out to first of all Tim Mais, but also Clemens Zweekhorst, Christian Capelle, Ibrahim Bouchataoui and Christophe Marichal.

Prof. Dr. Guido F. Smoorenburg, who supported the start-up of the clinical trial.

Dr. Margreet Langereis, who provided a fantastic amount of support for the clinical trial, even beyond her regular work hours. She has provided me a great deal of insight in how to guide cochlear implant recipients.

My parents, who supported me enormously the previous six years in pursuing my Master’s degree.

Last, but certainly not least, I would like to thank my beloved girlfriend, my friends and my colleagues at work who’ve supported me greatly throughout the final few months, which have been extremely stressful. I relish their understanding and efforts to keep me relaxed.

Please note that the names of actual companies and products mentioned herein may be the trademarks of their respective owners.
Summary

Cochlear implants are technical medical devices that allow individuals with severe to profound hearing loss to perceive sound. Speech and environmental sounds are picked up with the ear level microphone and sent to the speech processor. The speech processor filters, analyses and digitises the sound into coded signals. These signals are sent from the speech processor to the transmitting coil that sends the encoded information to the cochlear implant under the skin. This implant stimulates electrodes in the inner ear according to the information that was received.

These cochlear implant systems need to be programmed (fitted) specifically for each individual by an audiologist, which is a time-consuming process in a clinical environment. During these fitting sessions, the audiologist determines the lower and upper stimulation level thresholds for each of the 22 electrodes through a process that relies on subjective feedback from the recipient. Because the procedure is performed in a relatively unknown, clinical environment with an unknown speaker and the available time is limited, it can be argued that the resulting settings are not optimized for the recipient’s home environment.

Smoorenburg et al. (2002) have developed a ‘parametric’ fitting strategy that reduces the number of stimulation level variables. In this strategy, the upper and lower stimulation level profiles are described by four variables (overall level and overall slope of the profiles), while the basic form of the profiles is given by measurements of compound action potential thresholds. Not only does this reduce the workload but it also makes it possible to implement the controls to modify these stimulation settings on a speech processor.

This project (named PCIMAR, short for Parametric Cochlear Implant Map Adjustments by Recipients) was performed to implement the parametric fitting procedure on Cochlear’s L34 research speech-processor. The assembly-written firmware of the L34 was modified and additional software utilities were developed in Visual C++ to support the added functionality. The modifications provide the user visual feedback on the four variables. Adjustments to these parameters will result in recalculating the actual stimulation values, which is performed real-time.

The PCIMAR speech processor was tested in a clinical feasibility trial of 8 weeks with four subjects. In this trial, the subjects received a modified speech processor. Speech perception tests were performed multiple times during the trial. During the first 5 weeks, the subjects could adapt to both the new speech processor and the settings as created by Smoorenburg’s procedure. The self-adjustments could be performed during the final 3 weeks.

The results of this study show that recipients are able to adjust their stimulation level themselves in their home environment without generating extremely bad settings. The majority of the subjects showed stabilized settings for the maximum stimulation levels. Although there seems to be a trend that subjects perform better with their self-adjusted settings when compared to their conventional settings, this was not apparent when compared to previous test scores of the conventional settings. The test results therefore remain inconclusive. The subjective appreciation of the implemented functionality and the resulting settings was considerable. Two of the subjects even preferred their self-adjusted setting to their old one and are still using them today.
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1 Introduction

Cochlear implants are high-end technical medical devices that electrically stimulate the hearing nerve of the cochlea in the inner ear. These systems are aids for individuals with severe to profound sensorineural hearing loss in both ears who gain little or no benefit from hearing aids. With a cochlear implant, recipients (re)gain awareness of environmental sounds. Most users can understand speech without the necessity of lip-reading and some can use the telephone. A cochlear implant system converts sound into electric currents, which are delivered in the immediate vicinity of the auditory nerve in the cochlea. The auditory nerve is stimulated by these electric currents and transmits nerve impulses to the brain, where they are understood as acoustic sensations.

Research on cochlear implants for human use dates back to 1967. The currently available commercial systems show functionality that has been around since 1978. The technology is therefore quite new, which is e.g. demonstrated by the fact that the focus of the functionality of these systems has been to relay speech to the recipient, leaving other areas such as music perception quite uncharted. The process and physiology of human hearing is not completely clear. A lot of research is still being performed, not only on this area, but also to understand how cochlear implants act as a substitute and how they can be improved.

This specific project will focus on the latter. Cochlear implant systems need to be programmed specifically for each individual, which still takes a lot of time for both the clinician and the recipient because the process relies on subjective feedback from the recipient. Over the recent years, research has looked into the possibilities of reducing this workload by using objective physiologic measurements. This project will extend one of these particular procedures by providing the recipient some limited control over his/her settings through a specially designed device. This report will not only cover the design of this device, but also the validation that has been performed in a first human-use, experiment in which the recipients were able to test this new feature for three weeks in their home environment.

Part of this master thesis assignment was also an in-depth literature study into the functioning of human hearing, the way in which a cochlear implant tries to substitute this functionality and how electrophysiological measurements can aid in configuring these implants. The literature study was performed to provide a solid foundation for the project. Chapters 2 and 3 summarize this literature study. It is therefore mainly a summary of the different articles and books that are mentioned in the references. A separate report that that describes how the literature study was performed is included in the appendix.

This project was conducted at the Cochlear Technology Centre Europe (CTC) under the name "PCIMAR" which stands for Parametric Cochlear Implant Map Adjustments by Recipients. In this project, an existing speech processor was modified so that recipients can alter their threshold and maximum electrical stimulation levels of their Cochlear implant. The algorithm is based on Smoorenburg et al. (2002), who introduced four parameters that define these stimulation levels. Although compatibility of this speech processor with existing software was maintained, additional utilities to support the added functionality were also developed.
Because the project featured a modified speech processor in a clinical feasibility trial, it was necessary to verify this speech processor along with the additional utilities as an experimental medical device according to standard company procedures. To comply with these procedures, PCIMAR was performed following a tailored version of Cochlear's Design Control Process.

This meant that all necessary documentation needed to be provided on the requirements, functional and physical design and verification activities. The clinical trial itself required an approval after submission of the project proposal by the medical ethical committee of the University Medical Centre Utrecht. In total, the following documents were created:

<table>
<thead>
<tr>
<th>#</th>
<th>Document</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Project Management Plan with Checklist</td>
<td>Defines the scope, responsibilities, deliverables and schedule of the project.</td>
<td>CTC/CLTD</td>
</tr>
<tr>
<td>2</td>
<td>Use Cases</td>
<td>Describes the additional functionality and use-ability of PCIMAR controls.</td>
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<td>Requirements</td>
<td>Lists the specific requirements for the PCIMAR system.</td>
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<td>5</td>
<td>Preliminary Hazard Analysis</td>
<td>Identifies the areas of product risk specifically for the PCIMAR project and describes the controls for preventing these risks from occurring.</td>
<td>CTC/CLTD</td>
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<tr>
<td>6</td>
<td>Verification Plan</td>
<td>Outlines how the PCIMAR L34 system will be verified.</td>
<td>CTC</td>
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<tr>
<td>7</td>
<td>General Functionality Test Protocol</td>
<td>Describes the general functionality test procedures.</td>
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<tr>
<td>8</td>
<td>Additional Safety Test Protocol</td>
<td>Describes the additional safety test procedures.</td>
<td>CTC</td>
</tr>
<tr>
<td>9</td>
<td>General Functionality Test Report</td>
<td>Contains the results of the executed protocol.</td>
<td>CTC</td>
</tr>
<tr>
<td>10</td>
<td>Additional Safety Test Report</td>
<td>Contains the results of the executed protocol</td>
<td>CTC</td>
</tr>
<tr>
<td>11</td>
<td>Verification Summary</td>
<td>Discusses the outcomes of the verification tests.</td>
<td>CTC</td>
</tr>
<tr>
<td>12</td>
<td>Final Checklist</td>
<td>Ensures that all procedures have been accounted for. Must be completed before the clinical trial can be started.</td>
<td>CTC/CLTD</td>
</tr>
<tr>
<td>13</td>
<td>PCIMAR Protocol</td>
<td>Outlines the PCIMAR feasibility clinical trial.</td>
<td>UMC Utrecht Ethical Committee</td>
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<td>14</td>
<td>Additional PCIMAR L34 manual</td>
<td>Explains the PCIMAR functionality for users.</td>
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<td>15</td>
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As Table 1 shows, most documents were generated for use and review at CTC. The most important documents also needed a review from Cochlear Limited (CLTD) or Cochlear's senior management. The added checklist with the project management plan was provided to ultimately gather the approval to start the clinical trial in an easy way. Because this checklist was verified at the start of the project together with the project management plan, it wasn’t necessary to verify the checklist at the final stage of the project again from scratch. A signed-off checklist would then be sufficient to gain approval from senior management level.

Because research- and senior management would have already agreed with the project management plan and checklist, only the signed-off checklist would have to be reviewed at senior management level during the final stages of the project.

The design phase of the project will be explained in Chapter 4. It will become clear which and why existing technologies were used as a basis for the design. The design will be explained thoroughly with regard to functional and implementation details. Chapter 5 focuses on the clinical feasibility trial that has been performed to validate the design. The setup of the trial will be explained and all deviations from this protocol that took place will be mentioned. The results of the trial will be further discussed in Chapter 6. Chapter 7 will conclude the project. Finally, Chapter 8 will reflect upon the personal experiences of the author during the execution of the project.
2 Sound

Before taking a look into the world of cochlear implant systems, we may want to start by identifying some basic aspects of the natural phenomenon that they aim to convey to the recipient: sound, and in particular, speech.

2.1 SOUND PROPERTIES

Sound is produced by waves of compression and decompression transmitted in air or in other elastic media such as water. Sound propagates at about 335 m/s in air. The waves are associated with changes in pressure called sound pressure. The unit of sound pressure is N/m², but more commonly sound pressure is expressed as the sound pressure level (SPL) in decibels (dB):

\[ SPL = 20 \cdot \log\left(\frac{P}{P_R}\right) \]  

In this equation, \( P \) is the sound pressure and \( P_R \) is a reference pressure of about 0.0002 dyne/cm². If the absolute threshold for human hearing (1 dyne/cm²) is used as the reference pressure, the sound pressure is defined as the hearing level (HL) in dB.

Sound frequency is measured in cycles per second or Hertz (Hz). A sound can be described in terms of a sum of pure tones. A pure tone results from a sinusoidal wave at a particular frequency and is characterized by its frequency, its amplitude and phase. All complex sounds are mixtures of pure tones. Noise is a sound composed of many unrelated frequencies, and white noise is a mixture of all audible frequencies.

2.2 SOUND AND THE HUMAN EAR

The normal human ear is sensitive to pure tones with frequencies between about 20 and 20,000 Hz. The threshold for detection of a pure tone varies with its frequency. The lowest thresholds for human hearing are for pure tones of about 1,000 to 3,000 Hz. By definition, threshold at these frequencies is approximately 0 dB (reference pressure 0.0002 dynes/cm²). Sounds that exceed 100 dB can damage the peripheral auditory apparatus, and those over 120 dB can cause pain. The dynamic range of speech lies between about 50 to 75 dB. The most relevant frequencies in speech are in the range of 300 to 3,500 Hz.

2.3 SPEECH

Speech is a complex sound and comprises voiced and unvoiced sounds. Voiced sounds consist of a fundamental frequency and harmonic components produced by vocal cords. The vocal tract modifies this excitation signal causing formant and sometimes antiformant frequencies. Purely unvoiced sounds show no fundamental frequency. Airflow is forced through a vocal tract constriction at different locations between the glottis and lips. Unvoiced sounds usually contain less energy than voiced ones.

Whispering is a special case of speech in which the speech is only unvoiced. A small opening between the vocal folds generates air turbulence and the sound source is noisy.
Phoneticians divide speech sounds into vowels and consonants. All vowels, and some consonants ("m" and "n"), are voiced. A voiced waveform typically shows a repetitive waveform. This repetition rate is called the fundamental frequency ($F_0$) or voice pitch. For female speakers, this is typically 200 – 250 Hz. For a male speaker, it is typically 90 – 160 Hz. In most languages, the voice pitch does not carry information about the meaning of the words, although there are exceptions like Cantonese. When singing, the voice pitch carries the melody. Most of the energy of voiced sounds is located in low frequencies.

Unvoiced sounds (apart from whispering) are consonants. They show non-periodic and noisy waveforms and therefore do not show a voice pitch. Most of the energy of unvoiced sounds is located in higher frequencies.
3 Auditory perception

Chapter 3 provides a summary of the literature study that was performed to gain insight in the functionality of a cochlear implant with regard to normal human hearing and how electrophysiological measurements can aid in configuring these implants.

The functionality of a ‘healthy’ human ear is explained in Chapters 3.1 and 3.2. References [2], [5], [15] and [16] were mainly used in these sections. Chapters 3.3 and 3.4 will address the working of a cochlear implant according to references [4], [10], [15] and [16]. Chapter 3.5 will address the electrophysiological assessment tests that are used for cochlear implant recipients. Finally, Chapter 3.6 will address the way in which these cochlear implant systems are adjusted for individual recipients and how certain electrophysiological tests can be used in these procedures.

While the most parts of the literature have been summarized together, other parts that were already very clearly written in the documentation at hand were simply copied if this benefited the read-ability.

3.1 BASIC ANATOMY OF THE EAR

The ear can be subdivided into the external ear (or outer ear), the middle ear and the inner ear.

3.1.1 External ear

The external ear includes the pinna, the external auditory meatus and the auditory canal. The pinna helps in directing sounds into the auditory canal. The auditory canal transmits sound waves to the tympanic membrane.

![Figure 4 - The external ear](image)

In humans, the auditory canal has a resonant frequency of about 3,500 Hz and limits the frequencies that reach the tympanic membrane. [2] [5]

3.1.2 Middle ear

The external ear is separated from the middle ear by the tympanic membrane, better known as the eardrum. The middle ear contains air. A chain of ossicles connects the tympanic membrane to the oval window, a membrane covered opening in the bone of the inner ear. Adjacent to the oval window is the round window, another membrane-
covered opening between the middle and inner ears. The ossicles include the malleus, the incus and the stapes. [2]

![Figure 5 - The middle ear](image)

The stapes has a footplate that inserts into the oval window. Beneath the oval window is a fluid-filled component of the cochlea. This component is called the vestibule, which is continuous with a tubular structure known as the scala vestibuli, which is actually by definition a part of the inner ear, not the middle ear. Inward movement of the tympanic membrane by a sound pressure wave causes the chain of ossicles to push the footplate of the stapes into the oval window. This, in turn, displaces the fluid within the scala vestibuli. The pressure wave is transmitted through the basilar membrane of the cochlea to the scala tympani and causes the round window to bulge into the middle ear. [2]

The tympanic membrane and the chain of ossicles serve as an impedance matching device. Although the ear detects sound waves travelling in air, the neural transduction mechanism depends on movements established in the fluid column within the cochlea. Thus, pressure waves in air must be converted into pressure waves in fluid. The acoustic impedance of water is much higher than that of air (approximately $3600$ times). So, without impedance matching, most sound reaching the ear would simply be reflected. Impedance matching in the ear depends on the ratio of the surface area of the tympanic membrane to that of the oval window and on the mechanical advantage of the lever system formed by the ossicle chain. The efficiency of the impedance match is sufficient to improve hearing by $10$ to $20$ dB. [2]

There are also two muscles to be found in the middle ear: the tensor tympani and the stapedius. These muscles attach to the malleus and stapes respectively. When they contract, they dampen movements of the ossicular chain and so decrease the sensitivity of the acoustic apparatus. This action can be protective for sounds that can be anticipated, such as vocalization. However, a sudden increase in sound pressure level can still damage the acoustic apparatus, because reflex contraction of the middle ear muscles cannot occur quickly enough. [2]

Finally, the middle ear connects to the pharynx (extended part of the esophagus) through the Eustachian tube. Pressure differences between the external and middle ears can be equalized through this passage.

### 3.1.3 Inner ear

The inner ear includes the bony and membranous labyrinths, from which the cochlea and the vestibular apparatus are formed.
The cochlea is a spiral-shaped organ. The spiral in humans consists of 2½ turns, starting from a broad base and extending to a narrow apex. The cochlea forms from the rostral end of the bony and membranous labyrinths. The apex of the cochlea faces laterally. The bony labyrinth component of the cochlea includes several chambers. The vestibule is the space facing the oval window. Continuous with the vestibule is the scala vestibuli, a spiral-shaped tube that extends to the apex of the cochlea. The scala vestibuli meets the scala tympani at the apex. The connection point where these two components of the bony labyrinth merge is called the helicotrema. The scala tympani is another spiral-shaped tube that winds back down the cochlea to end at the round window. The bony core of the cochlea around which the scalae turn is called the modiolus. [2]

The membranous labyrinth component of the cochlea is the scala media, or cochlear duct. This membrane-bound spiral tube extends 35 mm along the cochlea between the scala vestibuli and scala tympani. One wall of the scala media is formed by the basilar membrane, another by Reissner’s membrane and also by the stria vascularis. Reissner’s membrane and the basilar membrane divide the cochlea along its length. [2]
Chapter 3 – Auditory perception

The spaces within the cochlea are filled with fluid. The fluid in the scala vestibuli and scala tympani is perilymph, which closely resembles cerebrospinal fluid. The fluid in the scala media is endolymph, which is very different. Endolymph contains a high concentration of K\(^+\) and a low concentration of Na\(^+\) ions. It resembles intracellular fluid in this respect. Endolymph has a positive potential which results in a large potential gradient (\(+/-\ 80\) mV) across the membranes of the cochlear hair cells (about 140 mV). [2]

The neural apparatus responsible for transduction of sound into electrical stimuli is the organ of Corti. The organ of Corti is located within the cochlear duct. It lies on the basilar membrane and consists of several components, which include three rows of outer hair cells, a single row of inner hair cells, a gelatinous tectorial membrane (which also runs along the length of the cochlea) and a number of types of supporting cells. The hair cells lie between the basilar membrane and the tectorial membrane. With humans, there are a total of 15,000 outer and 3,500 inner hair cells. A rigid scaffold is provided by the rods of Corti and the reticular lamina. The stereocilia that contact the tectorial membrane are found at the apex of the hair cells. [2] [5]

The organ of Corti is innervated by nerve fibres that belong to the cochlear division of the eighth cranial nerve. The 32,000 auditory afferent fibres in humans originate in sensory ganglion cells in the spiral ganglion, which is located within the modiolus. These nerve fibres penetrate the organ of Corti and terminate at the base of the hair cells. Those going to the outer hair cells pass through the tunnel of Corti, an opening below the rods of Corti. About 90% of the fibres end on inner hair cells and the
remainder on outer hair cells. This fact means that several afferent fibres diverge to supply many outer hair cells. In addition to afferent fibres, the organ of Corti is supplied by cochlear efferent fibres, which terminate on the outer hair cells and on the afferent fibres contacting the inner hair cells. The cochlear efferent fibres originate in the superior olivary nucleus of the brainstem and are often called olivocochlear fibres. [2] [5]

Figure 9 – Inner and outer hair cells

3.1.4 Auditory pathway
The auditory nerve fibres are connected to the dorsal cochlear nucleus and ventral cochlear nucleus via the cochlear nerve. From the dorsal and ventral cochlear nuclei, fibres pass to the superior olive in the brain stem, then upward to the lateral lemniscus, the inferior colliculus, the medial geniculate body and finally to the auditory cortex where the tones are perceived.

Figure 10 – Auditory pathway
3.2 NORMAL HEARING

3.2.1 Sound transduction

Sound waves cause the tympanic membrane to oscillate. These oscillations result in fluid movements within the scala vestibuli and scala tympani. Part of the hydraulic energy is used to displace the basilar membrane and, with it, the organ of Corti.

The response of the basilar membrane to sounds of different frequencies is strongly affected by its mechanical properties, which vary progressively from base to apex. At the base, the basilar membrane is relatively narrow and stiff, whereas at the apex, the basilar membrane is wider and much less stiff. This causes the base to respond best to high frequencies and the apex to low frequencies. Each point on the basilar membrane will respond best to a certain frequency called the characteristic frequency or best frequency. This characteristic frequency decreases monotonically with distance from the base. [2] [16]

![Basilar membrane behaviour](image)

It is believed that the tuning of the basilar membrane arises from two mechanisms: an active and a passive one. The passive mechanism depends on the mechanical properties of the basilar membrane and surrounding structures, displaying a roughly linear behaviour. The active mechanism depends on the outer hair cells being in good physiological condition, showing sharp tuning characteristics of the basilar membrane for low input sound levels. A second function of the active mechanism is to provide level-dependent amplification (gain) on the basilar membrane. This gain is greatest for low-level inputs (below 30 dB SPL), decreasing progressively with increasing levels up to 90/100 dB SPL, resulting in a compressive behaviour. For example, an increase from 50 to 60 dB SPL of an input level sinewave signal will result in an increase of the basilar membrane response by approximately 2.5 dB only. [16]

The stereocilia of the inner hair cells are bent because of the shear forces set up by the relative displacements of the basilar membrane and the tectorial membrane. When the stereocilia of an inner hair cell are moved in the direction toward the tallest cilium, the inner hair cell is depolarized. When the stereocilia are bent in the opposite direction, the inner hair cell is hyperpolarized. The exact function of the outer hair cells is still somewhat unclear. Probably, their function is to influence the mechanics of the cochlea in an active way. They have a motor function, changing their length, shape and stiffness in response to electric stimulation, therefore influencing the response of the basilar membrane to sound. [2] [16]
Chapter 3 – Auditory perception

The changes in membrane potential result from changes in cation conductance in membranes at the apical ends of the hair cells. The potential gradient that affects ion movement into the hair cells includes both the resting potential of the hair cells and the positive potential of the endolymph. The total gradient is about 140 mV. A change in membrane conductance in the apical membranes of the hair cells therefore results in a large current flow, which produces the receptor potential in these cells. [2]

Hair cells release an excitatory neurotransmitter (probably glutamate or aspartate) when they are depolarized. The transmitter produces a generator potential, which excites the cochlear afferent nerve fibres with which the hair cell synapses. Thus, oscillatory movements of the basilar membrane cause intermittent discharges of cochlear afferent nerve fibres. Most cochlear fibres fail to discharge in response to a particular sound frequency. One factor that influences which afferent fibre discharges is its location along the organ of Corti because of the already explained mechanical properties of the basilar membrane that acts as a frequency analyser. The stimulus is distributed along the organ of Corti in such a way that different hair cells will respond to different frequencies of sound: this is the basis for the place theory of hearing. In addition, hair cells located at different places along the organ of Corti are tuned to different frequencies because of differences in their stereocilia and in their biophysical properties. [2] [10] [15]

The activity of hair cells in the organ of Corti results in discharges in primary afferent fibres travelling in the cochlear nerve. The cell bodies of these nerve fibres are in the spiral ganglion; the peripheral processes end on hair cells, and the central processes terminate in the cochlear nuclei of the brainstem. Unlike most other primary afferent neurons, those of the eighth cranial nerve are bipolar cells with a myelin sheath around the cell bodies as well as around the axons. [2]

A cochlear afferent fibre discharges maximally when stimulated by a particular sound frequency, called the characteristic frequency of that fibre. Different aspects of an acoustic stimulus are encoded in the discharges of cochlear nerve fibres. Duration is signalled by the duration of activity, and intensity is signalled both by the amount of neural activity and by the number of fibres that discharge. For low frequency sounds up to 4,000 Hz, the frequency is signalled by the tendency of an afferent fibre to discharge in phase with the stimulus. This phenomenon is called phase locking. Phase locking is required for sounds with periods shorter than the absolutely refractory period, which limits neural discharges to rates lower than about 500 Hz. This means that a given fibre cannot discharge in each cycle for tones of 500 Hz or more. However, frequency information can be detected by the central nervous system from the activity of a population of afferent fibres, each of which discharges in phase with the stimulus. This is called the frequency theory of hearing. [2] [10]

The firing pattern of individual neurons is not completely predictable. In response to a sinewave, a spike will not occur for every cycle of a stimulus, although when spikes do occur, this happens at roughly the same phase of the waveform for each spike. The random variation in spike initiation is independent across neurons, resulting in a different spike pattern for each neuron in response to a sinewave. However, groups of adjacent neurons do show a firing pattern with spikes at every cycle of a stimulus. [10]
3.2.2 Coding of sound level
Loudness is a subjective attribute of sound and is related to an objective measure: the physical level. For sound levels above approximately 40 dB SPL, the loudness roughly doubles for each 10 dB increase in sound level. Although some research results are contradicting, it is commonly believed that sound levels are coded in terms of neural firing rate: a higher total spike rate that is evoked by a sound will result in a higher loudness experience. However, the neurons of the auditory nerve fibres also show spontaneous firing rates. The spontaneous firing rate depends mainly on the type of synapse with the inner hair cells: neurons with low thresholds have large sensitive synapses. They show high spontaneous firing rates and a nearly linear input-output function on the basilar membrane. The neurons with higher thresholds have less sensitive synapses, resulting in low spontaneous firing rates, a strong compressive nonlinearity and thus a wide dynamic range. Assuming that the level of sounds is coded in terms of neural firing rate, then, at high sound levels, the neurons with low spontaneous rates and wide dynamic ranges must play a crucial role. Neurons with high spontaneous firing rates make up for approximately 61% of the auditory nerve. Of the other neurons, 23% show medium spontaneous firing rates and 16% show low spontaneous firing rates. [16]

Without this spontaneous firing, neurons would either not fire at all, or fire when excited at or above their thresholds, resulting in an almost binary coded response. This makes it difficult to code small changes in level of a weak signal. The presence of stochastic noise, caused by the spontaneous firing of the neurons, prohibits this almost binary coded neural response, resulting in an increased dynamic range.

Information about the sound level and especially the relative levels of the different frequency components in complex sounds (such as speech) is also carried in the detailed time pattern of nerve spikes. This phenomenon called the frequency theory of hearing has already been explained in 3.2.1.

It is known from research (Heinz et al., 2001) that different places on the basilar membrane vibrate with different phases. In response to a single sinewave, the nerve spikes evoked at one place on the basilar membrane will occur at different times from those evoked at an adjacent place. Because the phase response of the basilar membrane varies with the sound level, Heinz et al. proposed that these changes provide a code for level: the phase changes may be detected by the pattern of responses across an array of neurons: each of these receive inputs from two auditory nerve fibres with slightly different characteristic frequencies. These neurons would fire only if the inputs from the two fibres are synchronous (across-frequency coincidence detector neurons). It is assumed that the conduction time from the instant of spike initiation to the coincidence detector is different for the two “input” neurons and that this difference varies across coincidence detectors. In response to a tone of fixed frequency, the coincidence detector that responds most strongly would vary with sound level. [16]

3.2.3 Coding of spectral shape
Sounds are processed by the ear in 24 sub-bands called critical bands. A critical band roughly corresponds to a constant distance on the basilar membrane. Within each critical band, sound signal intensities are additive. The width of these critical bands differs along the frequency range: below 500 Hz, the bandwidths are constant (100
Hz). Over 500 Hz, the width of each next critical band is 20% larger than of the band below. However, the definitions of these critical bands vary between researchers. The definitions of Zwicker [6] are most commonly used.

The perceived vowel-quality or timbre of complex sounds is determined partly by their spectral shape. The perception of timbre in a normal ear depends on the frequency analysis performed in the cochlea. Each vowel sound has a spectrum with peaks at specific frequencies (formant frequencies). The patterning of the formant frequencies plays a large role in determining vowel quality and vowel identity. Each point on the basilar membrane behaves like a bandpass filter, responding most strongly to a limited range of frequencies. The centre frequencies of these bandpass filters range from 50 to 15,000 Hz with a bandwidth of roughly 13% of the centre frequency for centre frequencies above approximately 1000 Hz. The ‘filters’ would show relative independent responses to a complex sound if the spacing were greater than the bandwidth of the filters. [16]

Spectral shape is represented by the relative response across filters, i.e. the magnitude of the response as a function of the centre frequency, which is sometimes called the excitation pattern. This relative level at the output of each filter may be coded in at least three ways [16]:

1) Coding by the relative firing rates of neurons as a function of the characteristic frequency. This is also called: the place code for spectral shape.

2) Coding by the relative amount of phase locking to the different frequency components in neurons with different characteristic frequencies.

3) Coding by across-frequency coincidence detection as described in 3.2.2.

3.2.4 Coding of frequency of sinewaves
The subjective pitch of a sinewave is closely related to its frequency: a higher frequency is perceived as a higher pitch. The classic place theory of pitch assumes that the pitch perception may be coded in the place of the basilar membrane that is excited the most. However, the position of the peak produced by a given frequency is level dependent: for high-frequency sinewaves, increasing the sound level causes the position of the peak in the vibration pattern to shift toward the base. If the classic place theory would be correct, this would mean that an increase of sound level results in a higher pitch perception. These changes in pitch perception have been recorded, but not to the extent that the place theory predicts. [15] [16]

A much better theory for pitch can be found in the phase locking effects as explained in Section 3.2.1. Because the nerve spikes tend to be synchronized to a particular phase of the stimulating waveform, the interspike intervals fall close to integer multiples of the period of the stimulus. Across-place coincidence detection may also be involved in the coding of frequency, because the phase difference between two specific points on the basilar membrane varies with the frequency of the input. [16]

3.2.5 Coding of periodicity and pitch of complex tones
Periodic complex sounds such as those produced by musical instruments and the human voice evoke a sense of pitch. The pitch that is heard is generally very close to
the pitch of the fundamental frequency of the complex sound. For example, if the sound has a repetition rate of 256 times per second, the fundamental frequency is 256 Hz and the pitch is close to that of a sinewave with a frequency of 256 Hz. When the fundamental component is removed from the sound, the pitch remains unaltered: it is then called the pitch of the missing fundamental, residue pitch, virtual pitch or simply low pitch. [16]

It is not completely clear how the perception of the low pitch of complex tones works. One theory assumes that the pitch of a complex tone is derived from neural information of the frequencies or pitches of the individual harmonics. The lower harmonics play the most important part in determining pitch, because these are the ones that are best resolved on the basilar membrane. This model therefore assumes that a central auditory mechanism computes the pitch by finding a best-fitting fundamental component.

A second model assumes that the pitch of a complex tone is related to the time intervals between nerve spikes in the auditory nerve. The pitch would then be derived from a place on the basilar membrane where harmonics interfere strongly.

Research indicates that both models can be applied. However, the clearest pitch is heard when low harmonics are present. Also, the ability to detect changes in repetition rate is best when low harmonics are present, leading to believe that a mechanism deriving pitch from the resolved harmonics is dominant. [16]

3.2.6 Binaural hearing

The advantage of having two normal ears seems obvious: differences in the intensity and time of arrival of sounds at the two ears provide cues that are used to localize sound sources in space and the ability to detect and discriminate signals in noise improves. Also, when dealing with a higher speech-in-noise ratio in one ear compared to the other (as a result of e.g. head-shadow effects), it seems that it is possible to make use of the ear receiving the higher ratio. The processing of interaural time delays in the normal auditory system probably involves a system of delay lines and coincidence detectors that are tonotopically organized. Essentially, the output of a given place in one ear is cross-correlated with the output from the corresponding place with the same characteristic frequency in the opposite ear. [2] [16]

3.2.7 Sound localization based on pinna cues

Sound localization depends partly on the use of high-frequency spectral cues, which are also available when only one ear is used. Some sound waves enter the meatus directly; others enter the meatus after reflection from one or more of the folds in the pinna or after reflection from the shoulders and torso. The direction-dependent interference effects that as a result occur in the spectral pattern provide information for localization. These spectral cues occur mainly at high frequencies of 6 kHz and above. [16]
3.3 COMPONENTS OF A COCHLEAR IMPLANT SYSTEM

A cochlear implant system produces electrical stimulation of the cochlea, enabling some rudimentary form of hearing perception for the recipient. A cochlear implant system typically consists of a microphone, speech processor, transmitter coil and an implant package, which comprises of a receiver stimulator and an electrode array existing of between 1 to 22 electrodes. Differences exist between the numerous cochlear implant systems depending on the used technologies or the brand (e.g. Cochlear, Advanced Bionics, MedEl, MXM). Although we will try to present an objective approach when describing these cochlear implant systems, the latest commercially available Nucleus system by Cochlear will be used as a reference.

3.3.1 Speech processor

Speech and environmental sounds are picked up at the ear level microphone and sent to the speech processor. The speech processor filters, analyzes and digitizes the sound into stimulation data for the implant package. This stimulation data is encoded in an FM (frequency modulated) signal, which is sent to the cochlear implant under the skin by a transmitting coil.

There are two different types of speech-processors: A body-worn speech processor (Figure 12) can be worn in a pocket, in a belt pouch or in a harness. An ear-level processor, which is usually called a behind-the-ear (short: BTE) speech processor (Figure 13) is worn behind the ear. The coil is held in position against the skin by a magnet and the microphone is worn behind the ear.
3.3.2 Implant package

The cochlear implant package (or receiver-stimulator) converts the coded information into electrical signals and delivers the appropriate electrical energy to the electrode array inside the cochlea. Figure 14 shows an impression of where the internal components of a cochlear implant system are typically placed.

![Figure 14 - Ear with implant](image)

The implant package is placed in the temporal bone. The implant contains the electronic circuits that control the flow of electrical pulses into the ear. It also contains a coil that receives the radio-frequency signal from the external coil and a magnet that holds it in place. Attached to the package are wire leads that join to electrodes.

![Figure 15 - Nucleus24 Contour implant](image)

Figure 15 shows Cochlear's Nucleus24 implant. The implant and receiver coil are clearly visible. The wires that extend from the implant are the electrodes, which are described in more detail in the next section 3.3.3.

3.3.3 Electrode array

The electrode array is inserted into the shell-like structure in the inner ear known as the cochlea. The preferred option is insertion to the scala tympani because it preserves
the frequency place coding of the normal hearing cochlea. This can be explained by looking at Figure 16.

This figure shows the theoretical locations of a perimodular electrode array at the different turns in the cochlea. These electrode arrays are designed in such a way that they can be placed in close proximity to the modiolus, which is preferred because it reduces the necessary stimulation current and therefore prolongs battery life.

Should the array have been inserted in the scala vestibuli, then the electrodes would have gotten closer to the spiral ganglion cells of the next turn, therefore causing smearing of the stimulation across the frequency range. Another disadvantage of insertion into the scala vestibuli is the increased complexity of the surgery.

Electrodes along the array stimulate the remaining nerve fibres in the cochlea. Next to these intracochlear electrodes, some implant systems (like Cochlear's Nucleus24 in Figure 15) also have two extracochlear electrodes which can serve as reference electrodes to the stimulating electrodes inside the cochlea: these extracochlear
Chapter 3 – Auditory perception

electrodes are the ball- and plate-electrode. The ball electrode is placed under a temporalis muscle near the ear. The plate electrode is located on the outside of the receiver-stimulator package.

![Diagram showing the placement of electrodes](image)

Figure 18 – Nucleus24 intracochlear electrode array

In the case that both the extra- and intracochlear electrodes are present, three different modes of electrical stimulation are available:

1) Bipolar stimulation
   With bipolar stimulation (Figure 19), the electrical current flows between two intra-cochlear electrodes: one active and one indifferent. This configuration allows for a localised site of stimulation, depending on the spatial separation of the two electrodes, which leads to the stimulation of a specific population of neurons. The spread of the current is more controlled when the bipolar pair is closer together. Standard bipolar configurations stimulate between two adjacent electrodes. If more remote electrodes are used, an extra number, e.g. BP+1, defines the stimulation by electrode spacing.

![Diagram showing bipolar stimulation](image)

Figure 19 – Bipolar Stimulation

2) Common ground stimulation
   When using common ground stimulation (Figure 20), current flows between an active electrode and all other electrodes in the array. There is no real advantage to this type of stimulation for daily use. In the days when it was not possible to measure electrode impedances, this type of stimulation was used to identify short circuits between electrodes after insertion.
3) Monopolar stimulation

Monopolar stimulation (Figure 21) uses one or both of the extracochlear electrodes to reference the electrodes inside the cochlea. Stimulating using the ball electrode is called MPI, stimulating using the plate electrode is called MP2 and stimulating using both the plate and ball electrode is called MP1+2. Although bipolar stimulation was thought to be the best solution for localised stimulation, monopolar stimulation has proven to perform equally well. On top of that, monopolar stimulation requires less current than bipolar stimulation.

3.4 HEARING THROUGH A COCHLEAR IMPLANT

In a profoundly hearing-impaired person, who would be a candidate for a cochlear implant, the inner hair cells are usually severely damaged or missing altogether. Also, the neurons that make up the auditory nerve may be partially degenerated. This means that the cochlear implant system should mimic the entire auditory processing of transforming mechanical into electrical energy.

As mentioned in 3.3, the functionality of a cochlear implant will be described as objectively as possible, however the latest commercially available Nucleus system by Cochlear will be used as the lead reference.
3.4.1 Speech processing
Speech processing by cochlear implants is perhaps best described as an activity that continuously analyses a speech sound signal, selects parameters according to a predetermined set of rules and embeds these parameters and their magnitudes in a carrier such as a digital electrical signal or an RF transmission. This entire process will be more clearly described in the following chapters. The most important parameters that define the electrical stimulation are:

- Stimulation electrode
- Reference electrode
- Amount of current provided by the stimulating electrode
- Stimulation rate and configuration

Cochlear implants convey both spectral and temporal information of sounds by electrical stimuli. However, there are limits to how many stimuli they can provide each second (the stimulation rate). Speech coding strategies therefore involve trade-offs between emphasising spectral and temporal information.

Typically, to stimulate a site in the cochlea electrically, a stimulus is generated by applying a positive voltage and then a negative voltage between two electrodes. This way, there will be no build-up of electrical charge. The absolute charge that is delivered is responsible for providing different levels of stimuli. The number of stimuli which may be delivered in one second is called the pulse rate. If shorter stimuli are applied, more stimuli can be delivered in one second. Typical rates that can be delivered by implants range from $250 - 2000$ Hz per electrode, making the total stimulation rates for a 22-electrode array vary between $1500 - 14400$ Hz.

While there are numerous differences between different speech processors, the overall signal flow remains the same: Input sound from the microphone is pre-processed by an analog front-end, which is in fact a preamplifier. This amplification is especially necessary for the higher frequency components to overcome the natural concentration of energy in the lower frequencies. The amount of gain can be controlled by the recipient through different controls (sensitivity control, automatic gain control or automatic sensitivity control) depending on the speech processor that is being used.

Automatic gain control monitors the input level sound and decreases the preamplifier gain whenever clipping of the amplifier is imminent. The sensitivity setting controls the maximum output level of the preamplifier. Automatic sensitivity control can be used to automatically adjust the sensitivity based on the (background) noise floor of the sound.

The next processing stage in speech processing is filterbank processing. A filterbank comprises of a number of band-pass filters that cover the input frequency range. The filterbank splits the input audio signal into a number of frequency bands and determines the energy in each band (Figure 22). The frequency bounds are based on critical bands (see also 3.2.3), roughly linearly spaced below $1000$ Hz and logarithmically spaced above $1000$ Hz. Each output band of the filterbank can be allocated to one or more electrode channels in the implant. Filterbanks are implemented using switched capacitor filters or DSP technology, depending on the speech processor.
In the ACE strategy, the output of the filterbank is sampled according to the speech coding strategy and the filterbank technology used. Usually, only a subset of filterbank outputs is used for electrode stimulation (Figure 23). Which filterbank outputs are selected is usually based on the amplitudes of the filterbank outputs. This is usually a dynamic process in which e.g. the 6 highest filterbank outputs are used.

The selected filterbank outputs are then allocated to specific electrodes. Usually, the number of channels equals the number of used electrodes but this configuration is not fixed and can be altered. The order in which the electrodes are stimulated depends on the chosen strategy, although it is common practice to stimulate the electrodes in a frequency-dependent order.
Up till now, the order of the electrodes in this stimulation frame has been determined. The next part of the speech processing determines how the selected electrodes perform the stimulation. This process uses a non-linear algorithm to cope with the non-linear psychophysical effects in normal hearing and transforms the filterbank amplitudes into a stimulation level that represents the loudness of that frequency component.

This stimulation level (CL)\(^1\) is represented by a value between 0 and 255. The relationship between the stimulation level CL and electrical current in \(\mu A\) is defined by equation (4.1). The 8 bit linear CL scale therefore covers a 40 dB log scale of electrical current between 17.5 \(\mu A\) (\(CL = 0\)) and 1.75 mA (\(CL = 255\)).

\[
I = 17.5 \cdot 100^{\frac{CL}{255}}
\]  

(4.1)\(^1\)

It is common practice within the cochlear implant industry and research to refer to the stimulation level using these linearly scaled CL units instead of electrical current. This stimulation level lies between a threshold stimulation level (T-level) and a maximum comfort level (C-level). These T- and C-levels vary between recipients and used speech coding strategies and are determined by an audiologist (see also Section 3.6.1).

Ultimately, the entire process has resulted in a defined stimulation pattern. Depending on the type of implant, stimulation by the implant may be analog or pulsatile. Pulsatile stimulation is more commonly used. The reason for this is that the most cochlear implants only have one current source, which means that they can only stimulate one electrode at a time. Simultaneous stimulation is therefore not possible. Because there is no point at stimulating electrodes sequentially with analog waveforms, pulsatile stimulation is widely used.

Depending on the chosen speech processing strategy and further configurations by the audiologist, the pulsatile stimulation (Figure 24) is defined by the following parameters:

- Stimulating electrode
- Reference electrode
- Stimulating current level
- Pulse width
- Inter-phase gap
- Stimulation rate

\(^1\) The use of the abbreviation CL for the stimulation level might seem a bit strange. It is however common practice within the world of cochlear implants to refer to this level as the "current level". Because the latter term would cause serious confusion for readers who are not that familiar with cochlear implants, we opted for the term stimulation level, represented with the symbol CL to keep the link with common cochlear implant research.
Finally, all stimulation information is encoded in radio frequency signals that can be sent to the implant through the transmitting coil.

3.4.2 Speech coding strategies
Until the mid 1990s, most speech coding strategies that were used in speech processors were based on feature extraction strategies. When using these kinds of strategies, the processor attempts to analyse the signal, identify any possible present key speech features and encode them as patterns of electrical stimulation. The key features that were looked for were the fundamental frequency (f0) and the amplitude and frequencies of the first and second formants (f1 and f2).

With this particular f0/f1/f2 strategy, stimulation frames were provided at a rate defined by f0 for voiced sounds or at random intervals of relatively low rates for unvoiced sounds. A stimulus frame consisted of stimulation of the selected electrode for f2 followed by stimulation of the selected electrode for f1. More information on this strategy can be found in [4].

While these speech coding strategies worked well for understanding single voices in quite environments, they proved to perform fairly bad with two simultaneous voices or in noisier environments.

With improvements in silicon chip technology and better safety of electrical stimulation, so called filter bank strategies could be developed, in which much more spectral and temporal information of the audio signal can be provided to the user. The number of filter bands, electrode channel number or pattern and even the channel stimulation rate all depend on the speech coding strategy and the configuration as selected by the audiologist.

Two very widely used speech processing strategies are CIS (Continuous Interleaved Sampling) and ACE (Advanced Combination Encoder).
Chapter 3 – Auditory perception

The CIS strategy (Figure 26) was developed at the Research Triangle Institute (USA). CIS emphasises temporal data by delivering a total stimulation rate that is sufficiently high to transfer the temporal characteristics of sound (3-5 kHz per channel) through a small number of fixed (typically 6 or 8) channels. It uses a fixed set of electrodes, regardless of changes in the incoming sounds. The number of used filter bands is also fixed. Because the electrodes are stimulated at a fast rate, detailed timing information of speech can be delivered.

The ACE strategy (Figure 27) is unique for Nucleus implant systems from Cochlear and was developed at the University of Melbourne for the CI24M implant. ACE combines spectral and temporal resolution in different amounts using a maximum of 22 frequency bands that all stimulate a specific electrode. The total stimulation rate can reach 14400 Hz when using the maximum possible 1800 Hz per channel using 8 active electrodes during each stimulation frame.
3.4.3 Coding of sound level

Sound levels are typically coded by pulse magnitude (current), by pulse duration or by a modulated analog current. An increase in any of these quantities will lead to an increased neural spike rate in the auditory nerve, which will be perceived as an increase in loudness. With electric stimulation, the spike rate increases very rapidly with an increase in current because the compressive behaviour of the basilar membrane is bypassed and refractory effects don’t occur, as the release of neurotransmitters is not required. This means that the range of currents between the detection threshold and the point at which an uncomfortable sensation occurs can be very small – typically ranging 3 to 20 dB on a current scale. The dynamic range of acoustic hearing is approximately 120 dB, so cochlear implants need some form of compression to map the wide range of input levels into the small usable range of currents. [16]

Many implant systems use an automatic gain control system in the front end as the first compression stage by filtering the input signal into several frequency bands. In some implant systems each bandpass filtered signal is fed directly to one electrode: this is called compressed analog stimulation. Other systems (e.g. CIS strategy) use the filtered signals to modulate rapid trains of biphasic current pulses (see 3.4.1). Further compression may be applied either to the analog signal or in the mapping from the magnitude of the analog signal to the pulse width or height. The different compression systems vary in the speed with which they react to changes in the magnitude of their input. A slow system would compensate for variations in overall sound level when changing from one listening situation to another: these systems could also be called automatic volume control systems. Fast compression systems are usually called syllabic compressors, because their gain changes over durations comparable to those of syllables. The compression systems that are used in cochlear implants can generally be described as ‘medium’ speed systems. [16]

The second compression stage is applied in the transformation of the magnitude of the analog signal to the pulse width or height and is often applied instantly: this would mimic the normal action of the cochlea, because the compression observed on the basilar membrane appears to be almost instantaneous. Compressing sound levels ranging 90 dB (30 dB to 120 dB SPL) to the typical dynamic range of currents at the
input to a single electrode (approximately 10 dB) would require a very high ratio of 9:1. [16]

Using a fast compression with such a high compression ratio would result in a severe reduction in speech intelligibility. Important information in speech is carried in the patterns of amplitude modulation in different frequency bands. Fast compression reduces the modulation depth, which adversely affects speech intelligibility with a compression ratio greater than two. If fast compression is used before the signal is split into different frequency bands, this can introduce spurious amplitude fluctuations, which are correlated across different frequency bands. This causes perceptual fusion of all bands, making it hard to separate target speech from background sounds. In implant systems using compressed analog stimulation, the modulation pattern may be distorted if fast compression is applied to the analog signal in each frequency band. [16]

The best solution would be to use a slow-acting front-end compressor, possibly with a supplementary “fast” component that prevents brief intense sounds from becoming uncomfortably loud. Then only a moderate amount of fast-acting compression is needed in the individual channels of the implant system. [16]

3.4.4 Coding of spectral shape
The coding of spectral shape in implants is done using the ‘place code’ approach. The signal is first filtered into several frequency bands, which are then mapped onto appropriate electrodes. The effective number of independent bands (channels) is less than in a normal ear, limited by the number of electrodes and the relative lack of isolation between electrodes.

Other problems arise because of [16]:

1) Mismapping in the allocation of frequency bands to electrodes. For example, the output of a channel that is centred at 1000 Hz may be used to drive an electrode at the 2000 Hz place within the cochlea. Although this affects sound perception, users may adapt to it with extended experience.

2) In implant systems using pulsatile stimulation, the electrode signals usually do not convey detailed temporal information relating to formant frequencies. This prevents phase locking to the different frequency components in neurons with different characteristic frequencies.

3) Across-channel coincidence detection does not take place, because the phase change across electrodes is not normal. Electrodes in regions of the cochlea without any neurons could be set to maximum stimulation levels during fitting because the current would then stimulate adjacent regions where there are surviving neurons. Effectively, this would cause a second type of mismapping.

3.4.5 Coding of frequency of sinewaves
In implants, frequency is also partly coded in the relative magnitude of the electric signal across channels. A single sinewave will result in an output largely restricted to a single electrode, which largely resembles the place code theory. Because of the small number of electrodes and the limited isolation between them, this is not a very...
accurate strategy. Low frequencies may also be coded in the time pattern of the signal applied to a single electrode. However, recipients show a poor ability to detect changes in the periodicity of the electric waveform applied to a single electrode. [16]

This is probably the case because [16]:

1) There is often a mismatch between temporal and place information, e.g. when a signal with a repetition rate of 500 Hz is delivered to a cochlear place that is tuned to 1000 Hz.

2) Phase differences across the basilar membrane that are generated by a travelling wave are absent. This prevents across-channel coincidence detection coding of frequency.

3) Partial degeneration of the auditory nerve may affect performance because there are fewer neurons carrying the temporal information.

3.4.6 Coding of periodicity and pitch of complex tones
Current methods of coding used in cochlear implants do not make effective use of the most important coding mechanism for pitch in the normal auditory system: the derivation of pitch from information about the frequencies of resolved harmonics. Except when the fundamental frequency of the input is relatively high, the lower harmonics in complex tones are usually not resolved by the filters of implant processors. Besides, the recipient would not be able to extract accurate information about the frequencies of individual harmonics anyway, because of the limitations in place and temporal coding. This leaves the coding of the periodicity of complex sounds almost entirely to a temporal code that is comparable to normal hearing when a complex sound contains only high harmonics. [16]

3.4.7 Binaural hearing
Commonly, cochlear implants are only implanted unilaterally. Bilateral implantation has shown to improve sound reception significantly, mainly because of the benefits with regard to head-shadow effects. However, bilateral recipients are unlikely to have the ability to use interaural time differences to localize sounds and improve the detection of sounds in noise restored. Of course, it is highly unlikely that the electrode arrays would be inserted to exactly the same depth in the two ears, so there would be a misalignment across ears, rendering it impossible for the recipient to measure interaural time delays. [16]

3.4.8 Sound localization based on pinna cues
Recipients do not have access to these spectral cues because the microphone is typically not located in the ear canal or at its entrance and because implants do not typically provide the detailed spectral information at high frequencies needed to make use of pinna cues. [16]

3.5 ELECTROPHYSIOLOGY
Electrophysiological assessment makes up an important component of most cochlear implant program. Most of the tests described here are derived from electrophysiological tests from conventional audiology. Instead of using acoustic stimuli, the tests have been adapted for use with electrical stimuli.
This chapter lists the electrophysiological tests most often used in the cochlear implant field. The information in this section is not necessary for a proper understanding of the current project, however, the different electrophysiological tests are mentioned for the sake of completeness and in light of background information that will help understand the research or Brown et al. (2000) and Smoorenburg et al. (2002) that will be addressed in Sections 3.6.2 and 3.6.3, respectively.

3.5.1 Electrically Evoked Auditory Brainstem Response
EABR measurements are the electrical equivalent of ABR (Auditory Brainstem Responses) measurements. ABR recordings are made by placing EEG skin electrodes on the forehead of the patient's scalp and on each earlobe. A series of tones, clicks and/or noise bursts are provided to each ear separately. The electrodes measure the electrophysiological response of the auditory pathway to the sounds.

EABR is the measurement of an electrophysiological response evoked by stimulation of the cochlear implant, instead of acoustical stimulation. Like in ABR, the response starts in the auditory nerve at the dendrites or spiral ganglion and travels through the nerve to the brain stem. The EABR wave pattern displays a number of consecutive neural action potentials that can be linked to the different 'stages' of the auditory processing system from the periphery up to and including the brainstem. EABR responses occur within 10 ms after the stimulus.

EABR provides information about the peripheral auditory nervous system, but it does not provide any additional information on the performance of the cochlear implant recipient. An absent EABR does not necessarily indicate a dysfunctional device because the response can be absent due to other technical or physiological reasons. Brown et al. (1994) assessed the relationship between EABR measurements and psychophysical T- and C-level thresholds. The reader is referred to this reference [8] and reference [3] for further information on EABR recordings.

Difficulties arise because movement of the recipient creates myogenic artefacts, which makes it necessary for the recipient to remain as still as possible. Recording EABRs in young children is therefore very cumbersome without the use of a sedative.

3.5.2 Electrically-Evoked Compound Action Potential
Stimulation of the auditory nerve either by sound or by an electric pulse causes action potentials that can be recorded with electrodes in the cochlea. When many fibres carry the action potentials synchronously, the resultant measurement is called a Compound Action Potential (CAP). If the synchronized action potentials are the result of an electrical stimulus (e.g. provided by a cochlear implant), the measurement is called an electrically-evoked compound action potential (ECAP).

The ECAP needs to be recorded in close proximity to the auditory nerve, which is best accomplished by placing an electrode in, or near the cochlea. An ECAP waveform (Figure 28) typically consists of an initial negative peak followed by a positive peak, labelled N1 and P1 respectively. The amplitude of the response (measured from N1 to P1) varies with stimulation level and across subject but typically reaches values of several hundred \( \mu V \). Note that the ECAP waveform is identical to the first wave appearing in the complex EABR pattern.
Chapter 3 – Auditory perception

The origin of the ECAP waveform has been investigated by Wai Kong Lai et al. (2000). Their model supports the view that the ECAP response is a result of two waveform components that originate from dendritic and axonal processes.

3.5.3 Neural Response Telemetry

Neural Response Telemetry (NRT) is a measuring system to record ECAPs and is implemented in the cochlear implant device. With NRT, the audiologist can specify the electrical stimulation at a certain electrode and measure the ECAP response at another specified neighbouring electrode. The implant amplifies, encodes and sends back the ECAP response measurement to the speech processor, allowing the software to display the information on-screen. Amongst others, Dillier et al. (2002) validated this technique. A protocol for recording the ECAP using NRT was derived by Abbas et al. (1999).

One of the major advantages of NRT over other ECAP or EABR techniques, is that it does not require external equipment other than the cochlear implant system. Compared to EABR, NRT is much less sensitive to myogenic interference and can easily be recorded in awake children. NRT has been found to work successfully with over 90% of recipients. At the end of this section, we will briefly discuss why NRT measurements are not possible with every recipient.

NRT can be used clinically to confirm that an implant is working correctly. Also, the observed physiological response can assist in estimating recipient’s threshold and comfortable maximum levels (see also Chapter 3.6).

The NRT threshold value, or T-NRT, is the highest stimulation level at which the difference between the N1 negative peak and P1 positive peak of the ECAP measurement (also called the ECAP amplitude) is zero. T-NRT values can be measured indirectly by extrapolating the N1-P1 results over a number of ECAP waveform recordings. This procedure is shown in Figure 29.
Chapter 3 – Auditory perception

The T-NRT value is obtained by recording a series of NRT waveforms for a series of stimulation levels. The values for the N1 and P1 amplitudes can either be selected manually by the clinician or automatically by the software. The resulting ECAP amplitude measurements can be plotted against the stimulating stimulation level. This plot is called the amplitude growth function. The T-NRT can finally be estimated visually or automatically by extrapolating the amplitude growth series to the point where the ECAP amplitude equals zero.

While the T-NRT value corresponds with the threshold for detecting a compound nerve response at a certain electrode, this does not necessarily mean that the T-NRT value equals the lowest stimulation level at which an auditory perception is perceived. Research has shown that there is only a moderate correlation between T-NRT (and other electrophysiological measurements for that matter) and the psychophysical (subjective) thresholds for stimulation. In general, the T-NRT value is somewhere between the softest perceivable level (T-level) and the highest level that is still comfortable (C-level), but results vary enormously, both intra- and inter-subject wise.

The deviations between the T-NRT and T-level profiles are probably due to varying amounts of neuronal decay between recipients. The T-NRT is based on ECAP measurements, which are compound nerve responses. It can be difficult to record such a compound action potential if the synchronicity between different nerve fibres is absent due to neuronal decay. This could also explain why it is impossible to measure ECAP values in some recipients. The absence of ECAP responses does therefore not necessarily mean that auditory perception at the same stimulation level is impossible. On the other hand, a stimulus that elicits an ECAP must also cause an audible sensation.
3.6 FITTING A SPEECH PROCESSOR

No two human beings are exactly the same. The condition of a recipient’s cochlea is as unique as a person’s fingerprint or retina. The process of programming the speech processor of the recipient and customizing it in such a way that the cochlear implant provides comfortable and useful stimulation is called ‘fitting’ the speech processor.

During a fitting session, the audiologist determines which electrodes of the implanted array can be used, selects a proper speech processing strategy and set the proper stimulation parameters. These settings together are called a MAP, which can be accessed by a program in the recipient’s speech processor.

The most important parameters of a MAP are:

- **The threshold stimulation setting for each channel (T-Level)**
  This setting, which is also called the “T-level”, equals the lowest level of electrical stimulation that consistently elicits an audible response. Hence, the softest sound being coded by the speech processor will cause stimulation at T-level.

- **The comfortable maximum stimulation setting for each channel (C-Level)**
  This setting, also called the “C-level”, equals the highest level of electrical stimulation that still gives a comfortable sensation. Hence, all sounds above this setting will be coded by the speech processor to stimulate at C-level.

- **The speech processing strategy**
  This is the algorithm that is used to transform sounds into electrical stimulation, e.g. Continuous Interleaved Sampling (CIS) or Advanced Combination Encoder (ACE). Although the ACE strategy will be the preferred option, the audiologist might opt to use the CIS strategy e.g. in case of a partially inserted electrode array.

- **The stimulation mode**
  The stimulation mode determines how the stimulation is controlled between the different electrodes, which can be monopolar, bipolar or common ground.

- **Channel and filter configuration**
  Some electrodes may not be used for various reasons and it may therefore be desired to allocate filter outputs to different channels.

The following sections will address a few different fitting strategies. The different strategies will be explained in the chronological order in which they evolved. It will become clear what the benefits and drawbacks of each strategy are. The final section will justify the technique that was used in the present study (which will be elaborated in Chapters 4 and 5).

3.6.1 Conventional fitting

During a conventional fitting session, the T- and C-level values are measured for all channels by slowly varying the stimulation current of one single channel.
Starting at a very low value, the T-level of each channel is measured by slowly increasing the stimulation current, until an auditory perception is elicited. Fine-tuning of the T-level is done in a so-called iterative up-down procedure by slightly in- and decreasing the stimulation current until the threshold stimulation level has been found. The C-levels are measured by slowly increasing the stimulation current further while asking the recipient to comment on the perceived loudness. C-levels are set when the sound becomes "loud, but comfortable".

This process takes up a vast amount of time, so the audiologist might opt not to measure all T- and C-levels but only the settings for a few channels. The T- and C-levels of the other channels can then be derived by interpolating between the measured values.

When all T- and C-levels have been obtained, the audiologist can start the speech processing by executing the MAP on a speech processor while staying connected to the computer. This process is called "live" mode and resembles the actual speech processing: the stimulation by the implant is determined by the environmental sounds that are picked up by the microphone and processed by the speech processor according to the MAP. The main advantage of this process is that the audiologist can quickly enable the MAP and verify the stimulation on the computer screen. That way, the efficiency of the MAP can be evaluated easily while adjustments can be made. If necessary, the MAP can be fine-tuned by repeating the entire process or parts of it.

A typical programming session of this kind can take up to two hours for an adult recipient and must be repeated over time to increase speech intelligibility to a satisfying level. Moreover, these fitting sessions are initially repeated every week.

We will from now on in this report use the term "conventional" to refer to this fitting strategy. When addressing distinctive T- and/or C-levels, the term "conventional" will also be used for the T- and C-levels that were obtained using this procedure. The term "psychophysically measured T/C-level" can also be used and has the same meaning.

3.6.2 Brown NRT based fitting strategy

Brown et al. (2000) and Hughes et al. (2000) performed extensive research on T-NRT measurements with adults and children, which resulted in a different fitting strategy.

Their research aimed to determine the relationship between ECAP and EABR measurements on the one hand and the T- and C-levels on the other hand. Brown performed linear regression analysis on the data from a group of 44 subjects by calculating correlation coefficients according to equation (4.2).

\[
\begin{align*}
\sum_{i=1}^{22} (x_i - \bar{x}) (y_i - \bar{y})
\end{align*}
\]

\[
\sqrt{\sum_{i=1}^{22} (x_i - \bar{x})^2 \cdot \sum_{i=1}^{22} (y_i - \bar{y})^2}
\]

A correlation coefficient of 0.547 was found for T-NRT and T-levels across electrodes and electrodes within subjects. The correlation coefficient between T-NRT and C-levels was 0.565.
These correlation coefficients are significant for a probability level $p$ of 0.001. However, they do not account for enough of the variance to justify a procedure that uses only the determined EAP thresholds to program the speech processor without additional measurements. Because the relationship between the T-NRT profile on one hand and the T- and C-levels on the other hand was fairly constant across electrodes, it was reasoned that the T-NRT measurements could be combined with a conventional psychophysical measurement of both the T- or C-level on one single electrode to better estimate the lowest and highest stimulation levels across the array.

Brown tested this theory as follows (Figure 30): First, the T-NRT values are determined for each of the 22 electrodes as shown in 3.5.3 (step 1). Next, the psychophysical T- and C-level are measured for channel 10 (steps 2 and 3). Other suitable channels can also be used. Finally the T- and C-level of each channel set to the same amount below and above the T-NRT value as channel 10 (steps 4 and 5).

![Figure 30 - Brown's fitting strategy example](image)

By applying this method, Brown found correlations coefficients between these NRT-based and conventional T- and C-levels to be 0.8 and 0.77 respectively when using the ECAP measurements together with measurements of the T- and C-level made on one electrode (usually electrode 10 of an intracochlear electrode with 22 electrodes). These results were obtained with all 44 adult recipients. Hughes reported these coefficients to be 0.85 and 0.89 when performing the same method with 20 children.

Brown also showed that these correlation coefficients were of similar magnitudes when EABR instead of ECAP measurements are used (0.831 and 0.905), which means that when T-NRT values cannot be obtained with a recipient, EABR measurements can be used instead.
This process of setting all T- and C-level values across the electrode array according to the T-NRT profile and psychophysical measurements of T- and C-level on one channel is regarded as a valid fitting strategy.

3.6.3 Smoorenburg’s NRT based parametric fitting strategy
Smoorenburg et al. (2002) used a different approach; they conducted principal components analysis (PCA) for the combined results of the T-, C- and T-NRT levels as well as the separate results of the T-level, C-level and T-NRT values for a group of 27 subjects. Using PCA, they identified the most important factors that contribute to all the data.

For a complete understanding of PCA, the reader is referred to [1]. For now, it is important to understand that PCA is used to identify certain patterns in data, called principal components. The eigenvalues for each principal component correspond to the amount of total variance in the data described by this component. A principal component is significant if its eigenvalue is greater than the corresponding value for the case of pure noise.

This analysis showed that the T-, C- and T-NRT profiles could be described by a number of principal components, of which the first two accounted for between roughly 96% and 98% of the variance for the combined results, the T-levels, the C-levels and the T-NRT values. The first component corresponds to the overall level, or shift, of the profiles and the second one to the slope, or tilt, of the profile.

As shown by Brown et al. (2000) and Hughes et al. (2000), the correlations between the T-NRT values and the conventional T- and C-levels are not very high. However, their research did not take into account that the variance between subjects can exceed the variance between electrodes in one subject and hence, the distinction between this inter- and intra-subject variance was not taken into consideration. Instead, the research focussed on correlation coefficients based on the variance across both subjects and electrodes within subjects. Because these two factors were not analysed separately, it is impossible to evaluate the extent to which these factors have contributed individually to the values of the coefficients.

The use of PCA yielded a different picture. The first component, representing overall level, showed correlation coefficients of 0.64 and 0.39 between the T-NRT and the conventional T- and C-levels, respectively. The second component, representing the tilt in the profiles, showed correlation coefficients of 0.82 and 0.36 between the ECAP thresholds and the conventional T- and C-levels, respectively.

Because the tilt of the T-level was closely correlated to the tilt of the T-NRT profile, Smoorenburg supported the assumption of Brown et al. (2000) that the T-NRT profile could be used as a basis for determining both T- and C-level profiles, but also hypothesized that the resulting T- and C-levels might be different if they were set without using conventional measurements of the T- and C-levels on one electrode. Instead, Smoorenburg proposed to shift the T-NRT profile around while performing the actual speech processing (the tilt component was not used in his experiment, for reasons that are beyond the scope of this text). The main difference of this method compared to the one as proposed by Brown is that the threshold and maximum
stimulation levels are obtained while stimulating multiple electrodes, thus also taking into account the possibility of loudness increase due to spatial and temporal summation effects.

To investigate this theory, a new fitting strategy was proposed that also uses the T-NRT profile as a basis for the MAP. In this strategy (which is demonstrated in Figure 31), the T- and C-level profiles are both set according to the determined T-NRT profile (step 1). Both the T- and C-levels are then set to as low as possible stimulation levels, with the C-level placed one CL unit above the T-level (step 2). This MAP is then activated to perform actual real-time speech processing during which the audiologist talks to the recipient (live mode). While keeping the speech processing active, the T- and C-levels are increased until the stimulation reaches a level at which the recipient starts to experience auditory perceptions. At this moment (step 3), the T-levels are fixed and only the C-level profile is further increased. The C-levels are fixed when they reach the point at which the stimulation becomes extremely loud (step 4). Smoorenburg called these newly found profiles the T-NEW and C-NEW levels.

![Figure 31 - Smoorenburg’s fitting strategy example](image)

When comparing conventional T- and C-levels with the T-NEW and C-NEW levels that were obtained using the method as proposed by Smoorenburg, the correlation coefficients became 0.87 and 0.94 for the first (shift) component.

As mentioned above, Smoorenburg’s experiment did not incorporate the tilt-component to determine the T-NEW and C-NEW levels. Nevertheless, the study showed that, for the majority of subjects, the NRT-based MAP yields speech reception scores (CVC words) close to those found for the existing conventional MAP. A minority of the recipients, however, showed scores for the NRT-based MAP up to 20% lower than those for the conventional MAP. The lower scores were found...
in those subjects having C-levels at the basal electrodes higher for NRT-based MAPs than for the previously used conventional MAPs.

The question arises whether these lower scores are due to habituation to the conventional adjustment, habituation reducing the acceptability of enhanced basal stimulation or reducing speech reception performance in view of the limited period given to adjust to the new stimulation, or even whether enhanced basal stimulation itself leads to lower speech intelligibility in these recipients. In any case, it is expected that when the tilt of the profile can be varied as well, performance of these recipients will increase. Smoorenburg's parametric fitting strategy is therefore extended by allowing the audiologist to further fine-tune the T- and C-level profiles of the MAP by adjusting the tilt of these profiles.

The shift and tilt adjustment values are not equal for all electrodes. Rather, the PCA that was performed on the MAP settings yielded shift and tilt factor score coefficients that vary among the different electrodes. These factor score coefficients show how much of the variance across the electrodes is explained by the different principal components. Figure 32 and Figure 32 show these values for the shift and tilt component.
As can be seen from the plots, the shift and tilt factors vary among the electrodes. This may not be that obvious for the shift component, but the tilt component shows a rather large deviation from zero at either ends of the array (electrodes 3 through 6 and 18 through 22) compared to the centre (electrodes 7 through 17). Electrodes one and two were excluded from Smoorenburg's research because the experiment was performed using the SPEAK strategy, which resembles ACE, but uses only 20 electrodes and a less high stimulation rate.

When adjustments are made to a MAP according to this fitting strategy, Smoorenburg's shift- and tilt-factor score coefficients need to be transformed to CL units before they can be applied. This transformation is done as shown in Equations (4.4) through (4.7).

Because the direction of the principal components is arbitrary, the values might be either positive or negative. As the shift factors turned out negative, a correction of \(-1\) was performed to turn the ultimate shift factors positive. Because the PCA performs the analysis based on correlations, it inherently performs normalization with regard to the standard deviations. As we are interested in actual CL unit values, this normalization must be corrected for, which is why the standard deviations for the T- and C-levels per electrode are applied. Finally, the results are multiplied by the standard deviations for the T- and C-level shift and tilt factors. By doing so, analyzing recipient data is easier because the standard deviations are already accounted for.

\[
\sigma = \sqrt{\frac{\sum_{i=1}^{20} (x_i - \bar{x})^2}{20}}
\]

(4.3)
In these equations, $F$ equals the factor score coefficient and $\sigma$ defines the standard deviation. The standard deviation of the T- and C-levels is found using equation (4.3), where $x$ equals the vector of either the T-levels or C-levels. The standard deviations of the principal components are determined by the PCA. The results of these transformations ($S$) are plotted in Figure 34 and Figure 35 and show the absolute variance of the different factors in CL units.
These plots show that the shift factor is much larger than the tilt factor. If the shift factor is increased by one standard deviation, the T- and/or C-levels are increased by roughly 15 to 20 CL units. On the other hand, an increase of the tilt factor by one standard deviation results in an increase of the basal electrode stimulation and a decrease of the apical electrode stimulation of approximately 4 CL units.

The main conclusions that can be drawn from the above, is that Smoorenburg showed that two components are sufficient to specify the T- and C-levels from the T-NRT profile. These components are the shift and the tilt transformations of the profile, the values of which differ across the electrodes. Using a new fitting strategy that shifts the T-NRT profile up- and downward to obtain the so-called T-NEW and C-NEW profiles, it was shown that for the shift-component, the correlation coefficient is 0.87 between the conventional T-level and the T-NEW profiles and 0.94 between the conventional C-level and C-NEW profiles. This means that the proposed fitting strategy is a valid way to quickly obtain proper T- and C-levels for all electrodes using only subjective responses from the recipient to indicate when the MAP becomes audible and when it becomes too loud. We will from now on in this report use the term "parametric" to refer to this fitting strategy.

In the present project, which we will describe in detail in the coming chapters, we will use this parametric fitting strategy as a basis. We will show that this fitting strategy does not exclusively need to be performed in a clinic. Rather, it will become clear that because of the reduction in parameters (4 shift and tilt parameters instead of 44 T- and C-levels), it is very well possible for a recipient to perform the adjustments of the T- and C-levels in their own environment.
Chapter 4: Project PCIMAR

Chapter 4 will deal with the start-up of the project and the actual design phase of the master thesis. Chapter 4.1 will give an introduction to the project. The actual boundary conditions for the design will be addressed in Chapter 4.2 and 4.3. Chapter 4.4 through 4.6 will then cover the main implementation phase of this project. It will describe how the design has been implemented and which problems needed to be solved. Finally, Chapter 4.7 will explain the verification and validation of the implementation.

4.1 INTRODUCTION

In this chapter we will discuss how to improve the currently widely used conventional fitting procedure for cochlear implant recipients. It will become clear what the problems are and what would need to be done to overcome them. Furthermore, we will show how the current project is related with the solution to these problems. Finally, we will globally describe the goals and the organization of the project.

4.1.1 Problem description

Cochlear implant systems need to be individually adjusted for each recipient. This procedure, which is called a fitting session, takes up a lot of time if performed according to the traditional method as explained in Section 3.6.1, usually 45 minutes weekly during the first three months. Moreover, it should only be performed by trained clinicians. Because of the nature of the currently used traditional fitting procedure, many issues still remain unresolved:

1) **Traditional fitting takes up too much time**

   Standard fitting procedures are very time consuming because each electrode needs to be individually adjusted. Not only does this cause a resource problem for cochlear implant clinics, but it is also inconvenient for the recipient. If implant electrodes continue to be designed in decreased sizes (creating the possibility of electrode arrays with many more electrodes), the time needed to perform a complete fitting session would also enormously increase which would enlarge this problem.

   → **Suggested course of action**: Reduce the time needed for fitting the recipient.

2) **Clinical environment is different from the home situation**

   Recipients are fitted in a clinical environment that clearly does not resemble in any way the natural environments of the recipient. It can be argued that the electrode levels that are obtained in this clinical environment do not fully provide the correct stimulation levels that are required in e.g. the recipient’s home environment, where other background noise is present.

   → **Suggested course of action**: Perform fitting or part of the fitting process in the home environment.
3) **Single electrode T-/C-levels do not resemble every-day use**

With traditional fitting strategies, the T- and C-levels are obtained for each electrode by providing the recipient narrowband stimulation. This doesn’t result in a direct relation between the provided stimulation and the stimulation during actual ‘live’ speech processing because any kind of loudness summation effects between electrodes is not accounted for. These loudness summation effects occur because of temporal and spatial summation as a result of electrical stimulation at adjacent electrodes. While it is true that the traditional fitting strategy yields a qualitatively good MAP, this does not mean that it is the only proper way to obtain the T- and C-levels.

→ **Suggested course of action:** Perform fitting using actual sounds, not single electrode stimulation.

4) **Recipient feedback is subjective**

Standard fitting procedures rely on the subjective feedback of the recipient in response to the provided stimulation – clearly not a very accurate, nor a scientific approach. Providing increasingly higher stimulation levels usually results in different auditory perception thresholds than would be obtained if the stimulation levels were slowly decreased. Also, the recipient grows accustomed to the fitting sessions, resulting in different subjective measurements. Finally, when fine-tuning a MAP, the recipient may have difficulty in guiding the clinician to the adjustments that would prove beneficial.

→ **Suggested course of action:** Guide the fitting process using objective measurements (ECAP or EABR) that are not influenced by the subjective feedback of the recipient.

5) **Subjective feedback of young children is not reliable**

The age at which cochlear implantation can be performed is still decreasing. Children as young as 2 months have been implanted. It is already very difficult for adults to provide the clinician with accurate subjective responses, but for children of young age, this is almost impossible. The only subjective measurements that the clinician can rely on in this case are facial expressions. On top of that, these very young recipients can’t stay focussed for long in a lasting fitting session.

→ **Suggested course of action:** Use objective measurements carefully to determine the fitting process.

Smoorenburg proposed a new NRT-based fitting method labelled ‘parametric fitting’ (see also Section 3.6.3) in which the MAP is based on T-NRT measurements, determined in live mode using only four parameters: the shift and tilt of as well the T-level and C-level profiles.

Although it is clear how one should set the shift values, at this moment there are no clinical guidelines for setting the tilt values of the MAP. The audiologist can vary the tilt of the MAP profile at random and ask the recipient which of the different speech processing settings sounds better. But often recipients find it difficult to judge the
quality of a MAP in the clinical environment, which is usually a quiet room with a relatively unknown speaker – a setting that clearly does not resemble the natural environments of the recipient. It can therefore be argued that recipients could benefit from a system that would enable them to further extend the fitting process themselves in their own home environment by fine-tuning their MAP.

Such a system however does not exist. Even the usefulness of such a system has never been investigated. The safety issues that arise when providing recipients control over their stimulation levels has probably held researchers reluctant to design a system with this functionality. The focus of this project is therefore to investigate the possibilities of a system that provides recipients these (limited) self-fitting controls and determine the extent to which this system would be feasible.

4.1.2 Project description

Originally, the idea of integrating parametric MAP control into a speech processor had been deemed to remain a technology development project at Cochlear’s Technology Centre. The proposition of expanding this technology project into a limited feasibility trial boosted the support for a full-time project which could serve as a master thesis work for a student of the TU/e at Cochlear: project PCIMAR. This abbreviation stands for Parametric Cochlear Implant Map Adjustment by Recipients and aims to demonstrate that recipients are able to adjust their own MAP parameters during normal day-to-day use, in a way that is either more efficient, or even qualitatively better than if the adjustments would have been made by the clinician.

To achieve this goal, the PCIMAR project strives to provide recipients the controls of Smoorenburg’s parametric fitting procedure on their take-home speech processor. The parametric fitting method as proposed by Smoorenburg (see also Section 3.6.3) is especially suited for self-fitting because it uses only four parameters: the shift and tilt of the T- and C-levels.

One could say that changing the shift factors of the MAP affect loudness perception and are hence related to some kind of volume control, while changing the tilt is like a tone control that changes the balance between high and low frequency sounds.

A speech processor that enables a kind of limited self-fitting (based on Smoorenburg’s parametric fitting), should be able to tackle most of the described issues with current standard fitting strategies. In analogy to the summary that was given in 4.1.1, the impact of the PCIMAR system can be described as followed:

1) Clinical fitting-process would be shortened
The time needed to perform a fitting session in the clinic would decrease substantially, therefore tackling the resource problem for cochlear implant clinics and decreasing the burden for recipients to spend a lot of time in the hospital.

2) The recipient’s familiar home environment is used during fitting
The recipient can fine-tune their stimulation levels in their home environment or adjust them for different environments, therefore optimising their MAPs within the environment that they are currently in.
3) **Fitting is performed using present speech**
Smoorenburg’s parametric fitting is performed with a MAP that uses all active electrodes during the complete speech processing, not by stimulating single electrodes at a time. Loudness summation effects due to temporal and spatial effects of adjacent stimulating electrodes are therefore already accounted for. Also, MAP fine-tuning is done with a completely audible MAP, which may enhance the performance and/or the recipient’s appreciation of the MAP.

4) **Objective measurements are used to guide the fitting**
Smoorenburg’s parametric fitting relies on NRT threshold measurements, so the profile of the T- and C-levels across the MAP is already fixed. The only subjective feedback that the recipient needs to provide during fitting is to indicate when the MAP turns audible or gets too loud. Fine-tuning of the MAP can be done by the recipient in their home environment.

5) **Limited self-fitting of children would not be advisable**
NRT based fitting strategies, like Smoorenburg’s parametric fitting, are much better suited for the fitting of children because they take up less time. Because of the experimental nature of the current study, limited self-fitting at home is not desirable in the case of children. As the concept of self-fitting is new, there is no data available that confirms the benefits or the risks of such procedures. Self-fitting, in any thinkable way, should therefore not be considered for children until enough data has been gathered during clinical testing of adults.

In order to test and validate these parametric controls over MAP parameters by the recipients themselves, the PCIMAR project not only foresees the development and implementation of a system that is able to provide all the controls of limited self-fitting: PCIMAR also aims to perform a limited feasibility clinical trial, which will feature the specially designed prototype speech processor in a first human use, take home experiment with four recipients. This trial will aid in evaluating how much the added controls have benefited the recipient in relation to the above-mentioned points 1-5.

4.1.3 **Project management**
The decision was made to put one student on the project for a timeframe of about 9 months. For this timeframe, a complete controlled design process needed to be scheduled. In the sections below, the different phases are listed:

- **PCIMAR start-up**
  PCIMAR had to be initiated, which required resource support and planning.

- **Requirements analysis**
  The requirements for the final design of the PCIMAR system had to be made. In parallel, the already existing technologies would have to be analysed to clarify which combination of available speech processor and fitting software should be used.

- **Design phase**
  The design had to be carried out and of course also implemented.
• **Verification phase**
The definitive design would have to be verified intensively to make sure that the designed system behaved exactly as specified in the requirements.

• **PCIMAR Clinical Trial start-up**
Parallel to all this tasks, the clinical trial had to be prepared and filed with the medical ethical committee to obtain approval.

• **Documentation**
Sufficient and in-depth documentation would have to be provided and reviewed in order to pass to different stages in the project.

• **PCIMAR Feasibility Clinical Trial**
The PCIMAR feasibility trial ultimately had to be performed. The outcomes of this trial would be an indication of the benefits and drawbacks of the proposed self-fitting concept. Positive outcomes could lead to an extended full-scale clinical trial.

The following sections will discuss all of these different parts of the project in more detail.

### 4.2 FUNCTIONAL REQUIREMENTS ANALYSIS

In this chapter the functional requirements will be determined according to the use cases and requirements as listed below. The main requirements were extracted by the parametric fitting procedure. This functional requirements analysis leads to a functional description which is the baseline for the implementation of the PCIMAR project. The system would need to consist of a speech processor, running programmable firmware and clinical PC software to provide the functionality to comply with the following main requirements:

1) **Real-time adjustments**
The user should be able to change the shift and tilt of the T- and C-levels independently and on the fly without noticeable cutouts in the audio streaming.

2) **Easy-of-use**
The controls should be easily accessible to the user. On a change of the acoustical environment for instance, the user should be able to adjust the parameters of the MAP very quickly.

3) **Logging**
All changes that are made to the parameters should be logged by the speech processor and should be retrievable by a PC.

4) **Guaranteed safety**
The audiologist should be able to set upper levels for each channel to prevent overstimulation. The speech processor should check continuously if this maximum is exceeded and stop all stimulation when that happens.
4.3 EXISTING PLATFORM SELECTION

An existing Cochlear platform was used for the implementation. The choice of which platform to choose was made by evaluating the already existing technology platforms with regard to the envisioned PCIMAR functionality. The speech processor and software would have to incorporate the following functionality:

The speech processor should:

- be capable of providing the recipient visual feedback regarding his/her MAP parameters,
- be equipped with a digital signal processing chip (DSP) for complex MAP calculations
- and be sufficiently flexible designed to allow firmware changes.

The fitting software should:

- provide the audiologist the ability to parametrically fit the recipient using Smoorenburg’s parametric coefficients
- and be able to program the speech processor that would be used in the trial.

It was soon clear that there was no single platform of speech processor and software that would satisfy all requirements. The platform evaluation in the next couple of paragraphs will show the pros and cons of each system.

4.3.1 Speech processors

Cochlear has developed several speech processors. It would have been nice to use a behind-the-ear speech processor for PCIMAR. However, given the fact that the current BTEs don’t have the benefits of a DSP or LCD, this would not have been a realistic choice. For this project, two alternatives were observed. The choice of which processor to use would determine the rest of the design phase for the most part.

The SPrint (Figure 12) is Cochlear’s current commercial body-worn speech processor. It supports NRT measurements and is equipped with a DSP and an LCD. However, the SPrint is not suited for PCIMAR because the LCD is too small to provide the recipient the necessary visual feedback.

The L34 (Figure 36) was the obvious choice for the PCIMAR project because it carries a much larger LCD, is equipped with a DSP and has a modular design. This modular design allows designers to modify (within limits) the firmware of this processor with e.g. adding user interface controls, or custom-made speech coding strategies. The L34 is one of Cochlear’s current research speech processors and therefore not commercially available. On top of this, a variety of software tools exist to retrieve information from the L34 that can be logged during a trial.
4.3.2 PCIMAR Technology Platform

The fitting software for the L34 is called NPE and stands for Nucleus Programming Environment. Unfortunately, the T- and C-levels can not yet be altered while running the speech coding strategy (live mode). This means that Smoorenburg’s parametric fitting strategy can not be performed using this speech processor. Also, the L34 does not support NRT measurements for the current commercial implants.

These problems are solved by using the SPrint speech processor for NRT measurements and parametric fitting. The SPrint is supported by a different software suite that consists of “R126” for fitting and “NRT 3” for performing NRT measurements. The final MAP can afterwards be entered manually into NPE to program the L34 speech processor.

One final problem however remained: how does one restrain the adjustments a recipient can make to their MAP settings? Audiologists focus greatly on possible overstimulation during a fitting session. Giving recipients complete freedom over their T-, but most of all, their C- levels would be careless to say the least. This meant that additional safety limits should be programmed into the speech processor for each recipient individually. Because this functionality is not provided by either R126 or NPE, an additional software utility needed to be created in the current project for this specific purpose.

4.4 PCIMAR SYSTEM OVERVIEW

Figure 37 shows a high-level overview of the PCIMAR system. In this overview, each functional block briefly describes the functionality and whether or not it was part of the PCIMAR design process. The light-grey rectangle shows the software part of the
system. All of the shown functionality will be explained in detail in the following chapters.

Figure 37 - PCIMAR System Overview

The R126 and NRT 3 software utilities together with a SPrint speech processor are needed for the NRT-based fitting of the recipient and will not be modified for PCIMAR. The NPE software has also not been changed because there was no time to complete the necessary extra verification procedures.

The PCIMAR project focuses mainly on the modifications to the L34 speech processor. The added, expanded or modified functionality of the standard L34 with regard to PCIMAR will be explained in Sections 4.5.2 through 4.5.6.

The PCIMAR programmer has been specifically designed for this project to program the speech processor indirectly with all necessary safety parameters and will be described in more detail in 4.6.1.

The CSLI tool, which is a script-based communication utility, is used to exchange data between the PC and the PCIMAR L34 speech processor. In this project, it will be used to extract the data from the clinical trial that will be gathered and stored in the speech processor. This means that only the necessary scripts to retrieve this data are designed without adjusting the tool itself. These scripts are described in Sections 4.6.2.
4.5 PCIMAR L34 SPEECH PROCESSOR

In this chapter, we will look into the changes that were made to the L34 speech processor. First, we will first describe the basic L34 speech processor as it was already available. We will then discuss the extensions that were made in this project.

4.5.1 Basic L34 Speech Processor

The L34 is a highly versatile speech processor with an integrated 8051 microcontroller ($\mu$C) for basic GUI control and a separate digital signal processing chip (DSP) which handles all speech coding and NRT calculations. The firmware of both the $\mu$C and the DSP is written in assembly language as it is the most efficient way to write (timing-sensitive) code. All PCIMAR related firmware was also developed in 8051 and DSP assembly code.

The L34 can store three user programs (MAPs) and provides volume and sensitivity control. The user interface of the L34 consists of a large graphical LCD and seven push buttons. The battery pack of the L34 consists of three AA (rechargeable) batteries, which can provide stimulation for about 18 to 22 hours, depending on the chosen speech processing strategy and RF level. The user interface is made up of a main menu that provides access to all other submenus, which is more clearly described below). Figure 38 shows a basic overview of the L34.

![Figure 38 - Basic L34 button overview](image)

Depending on the submenu of the L34 that is activated, the left, right and middle buttons all behave in a different manner. The menu, up, down and on/off buttons always have their unique function with the regular L34SP: the on/off button is used to turn the speech processor on and off, the menu button is used to access the options and the up and down buttons are used to adjust the sensitivity. Although these buttons each have their unique functionality, this may change for PCIMAR.

The L34 already has a simple menu structure that is accessible through the menu button (Figure 39).

![Figure 39 - Basic L34 menu overview](image)
The different submenus that are accessible provide the user access to all of the implemented functionality like volume control, mixing settings, the locking/unlocking of the buttons and LCD settings. For PCIMAR, an extra submenu would have to be added. Upon entering the menu in the standard L34 implementation, the ‘lock keys’ menu option is always available first.

4.5.2 PCIMAR extension

The PCIMAR functionality is available through an extra submenu “MAP adjustments”. Conveniently, this is implemented as the first visible submenu when entering the menu, leaving the other submenus simply shifted by one index as can be seen in Figure 40. Because the PCIMAR trial would be performed with native Dutch speakers, the term “map aanpassen” was used as a substitute.

![Figure 40 - PCIMAR L34 menu overview](image)

To be convenient to use, the PCIMAR submenu should be implemented in a very straightforward way, leaving at least most recipients capable of modifying their own MAP. The terms “shift” and “tilt” as well as “T-level” and “C-level” are therefore not usable. Together with professional clinical specialists, appropriate symbols and acronyms were considered.

The terms “T-level”, “C-level”, “shift” and “tilt” are not very intuitive for most recipients. Luckily, these parameters are clearly linked to the sound perception: variations in the shift parameter result in perceptual changes in loudness, whereas variations in the tilt parameter result in perceptual tone or pitch changes.

Ultimately, the term “loudness” (Dutch: “luidheid”) was chosen for the shift parameter and “pitch” (Dutch: “toonhoogte”) was chosen for the tilt parameter. “Tone” control would be no accurate description because it might confuse the user as ‘tone’ is not clearly linked to either higher or lower frequencies. The term “pitch” is more intuitive as more pitch will automatically be regarded as an increase in the higher frequency band.

In order to provide the recipient a clear overview of his MAP settings, all parameter adjustments that can be applied to one single profile (T- or C-level) have been put on one single screen. The definitive design of the PCIMAR adjustment screens is shown in Figure 41.
Adjustments to the various parameters, as well as the switching between T- and C-level adjustments are performed by simple button presses. The configuration of the buttons for the PCIMAR submenu is shown in Figure 42. Normally, the up and down buttons are reserved for sensitivity adjustments only. For PCIMAR, it was more logical to use these buttons as well for parametric adjustments.

As can be seen in Figure 42, for each profile, the loudness is increased by pressing the up button and the down button is used to decrease the loudness setting. The pitch is altered through the left and right buttons. By pressing the right button, the pitch can be increased, which in turn would lead to higher basal stimulation. A decrease of the pitch by pressing the left button will result in higher apical stimulation.

4.5.3 PCIMAR Adjustment limitations

The loudness and pitch adjustments that can be made on the speech processor are limited. For one, parametric MAP control is (for the moment) regarded as a fine-tuning of the MAP that the audiologist made. It is therefore not anticipated and also very unlikely that the recipient would want to change the MAP to an extremely ‘uncorrelated’ setting. On top of that, a very wide adjustment range could render the recipient ‘lost’ in his/her own parameter settings.

Secondly, unlimited adjustments would also be very unsafe. Adjustments to the T-level profile would do no immediate harm, although setting the T-levels too high would result in a strongly reduced dynamic range, which would probably decrease speech intelligibility. An even further increase of T-levels (up to C-level) would cause
continuous high stimulation levels, which should be avoided. C-levels on the other hand are already very close to maximum stimulation levels, above which stimulation should never occur. Small adjustments to the C-level loudness and pitch settings could therefore already provide uncomfortable or even painful stimulation.

Stimulation can occur at levels between 0 and 255 for each channel. The actual electrical currents that are linked to these levels have not been chosen randomly. The maximum level will provide uncomfortable and painful stimulation with most recipients, but most importantly: no tissue damage can ever occur. Although this makes a cochlear implant ‘safe’, C-levels have to be chosen very carefully because painful stimulation should be avoided at all times.

To prevent the recipient from diverging too much from the ‘standard’ audiologist’s MAP, it was decided that parametric adjustments are at all times limited to a range of two standard deviations, negative and positive, for as well the shift and tilt parameter with regard to the MAP that is made by the audiologist. As two standard deviations statistically cover the variance for 93% of the recipients, it was argued that this should provide a great enough degree of freedom to enable all recipients in adjusting their MAPs. The resolution of the adjustments to the parameters has been determined on one-tenth standard deviation. This means that the parametric adjustments can be made between −19 and +19 on the graphical user interface.

Avoiding overstimulation is a very different issue altogether. The limitation of allowing adjustments within two standard deviations of the tilt and shift parameter will certainly not prevent the possibility that the recipient adjusts the MAP to such an extent that (painful) overstimulation might occur. The stimulation level above which stimulation should be prohibited is called the loudest acceptable presentation level, short: LAPL.

These LAPL levels can be measured during a fitting session, but the fitting software does not allow the speech processor to be programmed with them. LAPL values should never be determined when stimulating separate electrodes individually as the temporal and spatial loudness summation effects due to electrical stimulation between adjacent electrodes are in that case not accounted for. A more detailed insight into how the LAPL levels are obtained during a fitting session is found in Section 5.1.3.

Because these LAPL values cannot be stored with every MAP using the existing software, a ‘workaround’ solution has been implemented. The LAPL values are added to the downloaded MAPs through the PCIMAR programmer. A detailed description of how the PCIMAR speech processor is programmed can be found in Section 4.6.1.

4.5.4 PCIMAR data logging
The PCIMAR L34 speech processor will be used in a clinical trial of which the outcomes are unclear. One could hypothesize that the ultimate setting would suit the recipient best, but it would also be wise to track the changes that have been made over time.

To keep track of the adjustments that the recipient performed using PCIMAR controls, the design also implemented a button press log specific for PCIMAR adjustments. This log could be read at any time to retrieve all past modifications.
The adjustments that are logged are:

1) **Successful booting of a PCIMAR enabled MAP**
   Every time a PCIMAR enabled map is booted, a number of safety checks, which will be discussed in Section 4.5.6.3, are performed. If these checks have been passed, the PCIMAR log will record the successful program boot. This event may occur if the speech processor is turned on, a PCIMAR enabled MAP is selected or if an active PCIMAR MAP has been reset.

2) **Failure at booting a PCIMAR enabled MAP**
   If one or more of the above-mentioned safety checks have failed, the PCIMAR log will record this program boot failure.

3) **Successfully performing a PCIMAR adjustment to the active MAP**
   Any modification to the tilt and shift parameters of the active MAP will undergo safety checks (see Section 4.5.6.3). If these checks have been passed, the PCIMAR log will record a successful parametric adjustment, indicating exactly which parameter was altered along with the new value. This includes increasing or decreasing of the tilt and shift values of both T- and C-level profiles.

4) **Failure at booting a PCIMAR enabled MAP**
   By the same argument, if a parametric adjustment has failed all mandatory safety checks, an entry will be added to the PCIMAR log.

5) **Resetting a PCIMAR enabled MAP**
   If a PCIMAR enabled MAP is reset, the current parametric adjustment values will also be reset to zero. This event is also logged in the PCIMAR history log.

6) **Resetting all MAPs**
   By the same argument, if all MAPs are reset and one of them has PCIMAR controls enabled, an entry will be added to the PCIMAR log.

7) **Detection of an abnormal device shutdown**
   For various reasons, all settings of the speech processor are stored when the device is turned off. This means that adjustments that have been made after the device has been turned on will not be stored if the device is not turned off correctly, e.g. if the battery is removed or a device failure occurs. Although this does not prevent the recipient to use the speech processor again, it does lead to differences between the latest PCIMAR log entries and the actually stored values. This could severely interfere with any meaningful scientific feedback in a clinical trial. To cope with this issue, the speech processor will check for large discrepancies between the PCIMAR log offset, which is stored every time the device is turned off, and the actual number of log entries. If such a discrepancy is found, an entry will be added to the PCIMAR log.

These log entries will specify at which time the actions were performed.
4.5.5 L34 PCIMAR communication dataflow

Figure 43 shows the flow of PCIMAR related data in the L34 speech processor. Although more actions are PCIMAR related, this chapter only covers the MAP adjustment routines as they are of the most importance to PCIMAR.

![Diagram of L34 PCIMAR adjustment data flow]

Any PCIMAR user action related to the adjustment of the active MAP is commenced by either booting a PCIMAR enabled MAP or performing a parametric adjustment. These actions are picked up by the \( \mu C \) after which a proper command is sent to the DSP. The DSP recalculates some of the MAP parameters according to the \( \mu C \) command. The \( \mu C \) is then told if the MAP adjustments were carried through. Finally, the \( \mu C \) accordingly adds an entry to the PCIMAR log.

4.5.5.1 \( \mu C \) implementation

Figure 44 shows how a PCIMAR MAP is booted. Normally, a command would be sent to the DSP to start the stimulation of the correct user program. However, since the standard MAP settings reside in secured ROM data on the speech processor, these values cannot be written with every change.

![Diagram of L34 \( \mu C \) PCIMAR MAP boot]

With each program boot, the \( \mu C \) first retrieves the last known parametric adjustment values of the selected user program. To avoid errors due to data corruption, these values are first checked for their general limitations. If the values appear to be valid, the DSP is contacted to adjust the MAP with these coefficients. If the DSP acknowledges the adjustment values, the MAP is made active and stimulation will start.

Figure 45 shows how the \( \mu C \) deals with user input and DSP communication when adjusting a MAP during stimulation.
A user request to change a certain parameter (T- or C-level tilt or shift) will first be checked against the general limitation of only permitting adjustments within two standard deviations (see Section 4.5.3). If these limits have not been exceeded, the DSP is contacted to perform a MAP adjustment. If this adjustment has been performed successfully, the LCD is updated with the new value. If the adjustment has not been performed correctly, the LCD will show an error message informing the user of this. Finally, an entry is made into the PCIMAR log on the result of this adjustment.

When writing a log entry, the current time and date are included. However, the circuitry of the L34 that keeps track of the time and date needs power from the AA batteries. These settings will become lost when the batteries are removed for about 15 minutes or more. Because the log entries provide important information during the clinical trial, users should be instructed to keep their time and date settings correct.

4.5.5.2 **DSP**
Regarding PCIMAR, the DSP is mainly responsible for recalculating MAP settings. Figure 46 shows the data flow within the DSP.

If the DSP detects a PCIMAR adjustment request, it will check if a MAP is being booted or if an active MAP is being adjusted. If a MAP is booted, more extensive calculations will need to be made.

4.5.6 **MAP recalculation**
The main focus of the PCIMAR project is the actual process of recalculating certain MAP coefficients that result in different T- and C-levels. PCIMAR is based on
Smoorenburg et al. (2002) and will therefore use the coefficients that were derived in this research.

However, as explained in 3.6.3, these parameters don’t show a clear linear behaviour across the electrode array. This means that recalculating certain coefficients would certainly require intense computational power, especially if the calculations need to be done (quasi) real-time, or at least fast enough so that the recipient experiences a smooth MAP adjustment.

This chapter will discuss which stimulation parameters are affected in what way by the PCIMAR adjustments as made by the recipient.

4.5.6.1 PCIMAR calculations in the speech-coding
As explained in 3.4.1, part of the speech processing is performed by transforming the filterbank outputs into CL units. This transformation is best described using equation (5.1), in which $e$ defines the electrode number and $T$ and $C$ represent the channel’s T- and C-level settings.

$$
Output_{\text{transformation}}(e) = T(e) + (C(e) - T(e)) \cdot NLC(Output_{\text{filterbank}}(e))
$$

(5.1)

As equation (5.1) shows, part of the transformation is done by applying a logarithmic compression to the filterbank outputs. This non-linear compression (NLC) is performed to cope with the non-linear psychophysical effects in normal hearing. Fortunately, the NLC is not influenced by changes to the T- and C-levels. This means that the PCIMAR calculations are best performed after this non-linear process has taken place.

In practice however, the speech processor does not perform the transformation using the output of the NLC together the T- and C-level, as one might expect. Instead, the normalized T-level (5.2) and dynamic range (5.3) are used.

$$
A(e) = \frac{T(e)}{255} = T_{\text{norm}}(e)
$$

(5.2)

$$
B(e) = \frac{C(e) - T(e)}{255} = C_{\text{norm}}(e) - T_{\text{norm}}(e)
$$

(5.3)

$A$ is defined as the normalized threshold stimulation value and $B$ is defined as the normalized dynamic range. The normalization is done with respects to 255 CL units because the DSP operates in the 1.15 format, in which all variables are described as a floating number ranging from -1 to +1. This is more clearly described in 4.6.1.

4.5.6.2 Modifying stimulation levels
Depending on the specific adjustment that is being made, either the T-level or C-level needs to be modified with the appropriate PCIMAR coefficients:
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\[ p_{\text{Ctilt}}^C(e) : \text{C-level tilt adjustment coefficients} \]
\[ p_{\text{Cshift}}^C(e) : \text{C-level shift adjustment coefficients} \]
\[ p_{\text{Ttilt}}^T(e) : \text{T-level tilt adjustment coefficients} \]
\[ p_{\text{Tshift}}^T(e) : \text{T-level shift adjustment coefficients} \]

All of these coefficients are taken from Smoorenburg et al. (2002) and differ for each electrode. These are the same profiles as plotted in Figure 34 and Figure 35, however divided by 10 so the user can make the adjustments as accurate as one tenth standard deviation. The adjustment values are also normalized by 255 stimulation levels to assure compatibility with the other variables that are used for speech processing. An overview of these values can be found in appendix B.

As mentioned in 4.5.3, MAP modifications by the user are possible between two standard deviations with a resolution of one-tenth standard deviation. Because of these restrictions and the chosen resolution, these modifier values, (defined in equation (5.5)) can range from -19 to +19. These PCIMAR modifier values are equal to the values that are displayed on the LCD as feedback for the recipient.

\[ \kappa : \text{C-level tilt modifier} \]
\[ \lambda : \text{C-level shift modifier} \]
\[ \mu : \text{T-level tilt modifier} \]
\[ \nu : \text{T-level shift modifier} \]

If a MAP adjustment is being made, these PCIMAR modifiers, together with the PCIMAR coefficients and the original (normalised) T-level and C-level values, determine the new values for the (normalised) T- and C-levels, which are defined as \( T' \) and \( C' \).

\[ C'_\text{norm}(e) = C_{\text{norm}}(e) + \kappa \cdot p_{\text{Ctilt}}^C(e) + \lambda \cdot p_{\text{Cshift}}^C(e) \] (5.6)
\[ T'_\text{norm}(e) = T_{\text{norm}}(e) + \mu \cdot p_{\text{Ttilt}}^T(e) + \nu \cdot p_{\text{Tshift}}^T(e) \] (5.7)

Because the DSP calculations use the parameters as defined in equation (5.2) and (5.3), combining these equations with (5.6) and (5.7) yields (5.8) and (5.10), which are the actual calculations as performed by the DSP.

\[ A'(e) = T'_{\text{norm}}(e) = A(e) + \mu \cdot p_{\text{Ttilt}}^T(e) + \nu \cdot p_{\text{Tshift}}^T(e) \] (5.8)
\[ B'(e) = C'_{\text{norm}}(e) + \kappa \cdot p_{\text{Ctilt}}^C(e) + \lambda \cdot p_{\text{Cshift}}^C(e) - T_{\text{norm}}(e) - \mu \cdot p_{\text{Ttilt}}^T(e) - \nu \cdot p_{\text{Tshift}}^T(e) \] (5.9)
\[ B'(e) = B(e) + \kappa \cdot p_{\text{Ctilt}}^C(e) + \lambda \cdot p_{\text{Cshift}}^C(e) - \mu \cdot p_{\text{Ttilt}}^T(e) - \nu \cdot p_{\text{Tshift}}^T(e) \] (5.10)

Figure 45 shows an example of these calculations. In this plot, the original C-levels are set to 180 CL units for each electrode. The original T-levels start at 90 CL units for electrode 22 and increased linearly to 132 CL units for electrode 1.
T- and C-levels are found by applying the following values for the PCIMAR modifiers: $\kappa = -20$, $\lambda = 6$, $\mu = 7$ and $\nu = -14$.

![Graph showing T- and C-levels](image_url)

**Figure 47 - PCIMAR Demonstration**

### 4.5.6.3 Safety procedures

While PCIMAR does provide recipients the opportunity to adjust their stimulation parameters, unlimited adjustments are not possible. Next to the general limitations as mentioned in 4.5.3, additional limitations may exist as a result of the T-level and C-level profiles. Any adjustment must comply with the following safety requirements:

1) The adjustment may not cause the T-level to exceed the C-level on any channel. The T-level and C-level stimulation values on each channel must also always differ by at least one stimulation level.

$$ C \geq T + 1 $$

(5.11)

2) The C-level stimulation value may never exceed the LAPL value. C-level stimulation at LAPL level is permitted.

$$ C \leq LAPL $$

(5.12)

3) The T-level stimulation value must be equal or greater than zero.

$$ T \geq 0 $$

(5.13)

All of these safety checks are performed by the DSP after the complete MAP recalculations have been performed.
On top of that, PCIMAR also uses a fail-safe mechanism that is already present in the L34 speech processor. Normally, the output value of the NLC module is used as the stimulation parameter $A_{\text{stim}}$. The L34 speech processor has also been designed with a MAX parameter. Just before the $NLC_{\text{output}}$ value is encoded in RF data for transmission to the implant, the L34 checks if the value is lower than the pre-programmed MAX value. This check is performed for each stimulation channel. If the value exceeds the MAX value, the stimulation level is clipped to this value.

$$\begin{align*}
\text{If } NLC_{\text{output}} \leq \text{LAPL} \text{ then } A_{\text{stim}} &= NLC_{\text{output}} \\
\text{if } NLC_{\text{output}} > \text{LAPL} \text{ then } A_{\text{stim}} &= \text{LAPL}
\end{align*}$$ (5.14)

With PCIMAR, the MAX values are initialised to the proper LAPL values at each program boot. If for some reason (e.g. data corruption) the safety procedures fail, this will ensure that stimulation can never occur above LAPL.

4.6 PCIMAR SOFTWARE

The additional software needed for the PCIMAR project consists of two tools, one for programming PCIMAR specific settings in the speech processor and a second one for clinical data retrieval from the speech processor during or at the end of the clinical trial. All necessary PCIMAR software utilities (LAPL programmer and the Data Decoder) are Windows applications, written in the C++ environment of Visual Studio .NET.

As mentioned in Section 4.5.3, certain absolute limits (LAPL) exist for the C-level adjustment. These LAPL values differ between recipients and must be programmed in the MAP of the speech processor as well. Because NPE does not provide the possibility of programming LAPL values with the MAP to the speech processor, this process must be done manually with an additional software utility: the PCIMAR programmer.

The tool that will be used to retrieve the recorded PCIMAR related actions from the speech processor is a Cochlear application tool, called “CSLI”, which is short for CIP Script Language Interpreter. CIP stands for Command Interface Protocol.

4.6.1 PCIMAR programmer

Internally, the L34 speech processor comprises of two parts of firmware: system and application level. PCIMAR has been integrated in both parts of the system.

For a proper understanding of the PCIMAR speech processor, it is not required to explain the differences between system and application code in detail. The system code is basically the operating system of the L34 and cannot be updated when downloading MAPs using NPE. The application code however does allow updates.

Each version of the NPE software is included with the corresponding version of the L34 firmware file. This file is written using XML language, which is a flexible and easy format for defining specific, custom-made document types. The XML file holds all the code and data that is to be programmed to the L34. The fitting software uses the XML file as a basis to program the speech processor. Once the MAP settings have been determined, the application code for the DSP is updated and used to program the
L34 speech processor. LAPL values can’t be downloaded this way because they cannot be configured in the MAP using NPE. For this purpose, the PCIMAR programmer is added to the programming procedure of the L34.

The PCIMAR programmer is used to embed these LAPL values in the firmware of the speech processor. To accomplish this, the PCIMAR programmer reads the L34 XML firmware file completely on start-up. It then looks for a specific data block in this XML file, which has been designed to carry the LAPL values. The user can then enter the LAPL values for each user program of the speech processor and update the LAPL blocks in the XML file when ready. When the utility is closed, the newly programmed LAPL values have been embedded in the XML file and the file is saved. When the MAPs are downloaded to the speech programmer, these LAPL values are automatically copied with them as they reside in the application data blocks, which are always invoked when a MAP is loaded.

![PCIMAR programmer screenshot](image)

Effectively, the utility converts the LAPL values (which can range from 0 to 255) into fractional DSP 1.15 hexadecimal representation. Because all values in the DSP are normalized, the LAPL values are divided by 255. The result is converted into a 2-byte 1.15 DSP representation. In the 1.15 notation, the MSB indicates if the value is positive or negative. The other 15 bits represent a value between 0 and 1 as shown in Figure 49.

![DSP 1.15 Bit Weighting](image)
Values that are written in the 1.15 format can therefore range between -1 (0x8000) and 0.999969 (0x7FFF) with a resolution of 0.000031 (0x0001). Equation (5.15) shows how the values can be easily calculated. The equitation is true only for the bitwise representation. The decimal LAPL value is shifted by 16 bits and normalized. This value can easily be converted into a hexadecimal representation by the standard C++ libraries.

\[ \text{LAPL}_{1.15} = \frac{32768}{255} \cdot \text{LAPL}_{\text{Decimal}} \]  

(5.15)

As a result, a LAPL value of e.g. 176 will be stored as 0x5858.

**4.6.2 PCIMAR CSLI scripts**

The CSLI utility is an internal Cochlear development tool. It uses a programming language that is quite similar to QuickBasic and is therefore very efficient to create small automated procedures.

The CSLI tool is used in this project to retrieve the data that was stored in the L34 speech processor during the clinical trial. This data is stored in the L34 in a fixed pattern. This pattern is shown in Figure 50.

![Figure 50 - PCIMAR data record layout](image)

For each data record, also the occurrence time is recorded. This way, the data can always be traced back to a certain moment. The "action" byte contains information on the PCIMAR related event that was executed. The value also shows if the event was successful (e.g. if a PCIMAR MAP adjustment was carried through or denied by the DSP after validating the change). The "value" byte is only used for parametric MAP modifications and contains the desired value of the corresponding shift or tilt parameter.

The CSLI PCIMAR data retrieval script reads all PCIMAR related data from the L34 speech processor and stores it in a text-based file for further analysis.

**4.6.3 PCIMAR data decoder**

Unfortunately, the CSLI tool is not very suited for displaying large sums of data on-screen. Because the PCIMAR log can contain up to about 9300 entries, browsing through this large amount of numeric values can be quite cumbersome.

To overcome this problem, a separate utility was developed: the PCIMAR data decoder. A screenshot of this utility is shown in Figure 51.
The utility works very straightforward. Using the “open file” button, the user can select a valid text-based output file that has been generated by the CSLI PCIMAR data retrieval script. The data decoder reads each log entry and shows the information in one large table on-screen. The user can now easily browse through the data using the scrollbar.

4.7 VERIFICATION AND VALIDATION

The objective of the PCIMAR verification process was to assure that the PCIMAR system and all its associated components meet their specifications through a structured set of verification activities. The verification procedures check that the implementation performs as supposed to the listed requirements in Section 4.1.2 and 4.2. The validation of the PCIMAR project includes the clinical trial and checks that all the user requirements are fulfilled and the functionality is implemented.

The verification activities have assessed general functionality issues as well as system compatibility testing, but with regard to the clinical trial, the larger part of the verification has focussed on safety issues.

The general functionality tests focussed greatly on the user interaction with the PCIMAR L34 speech processor:

- Different combinations of button presses were evaluated, making certain that nothing that the user does could lead to a device failure or crash

Figure 51 – PCIMAR Data Decoder screenshot
• The displayed text was tested to be correct in every situation, e.g. making sure, there were no discrepancies between the current PCIMAR modifier settings and the values as shown on the display.

• The DSP MAP recalculation algorithms were verified to yield correct results under a large number of circumstances. It was also verified that the adjustments were performed real time, which means that the calculations can be performed between two stimulation frames.

• The PCIMAR programmer was verified extensively to make sure that the LAPL values that were entered would also be transformed correctly into the L34 PCIMAR firmware file.

• The logging functionality of the PCIMAR routines were checked for correctness.

The additional safety tests focussed in more depth on the safety procedures that were implemented:

• A general safety verification was performed to make sure that possible errors could not result in overstimulation. This incorporates tests to cover the following:

  1) Recover from corrupt MAP data in the non-volatile, μC and DSP RAM.
  2) Checking the correct functioning of the DSP and μC watchdogs.
  3) Checking the communication between the μC and DSP.

• Different tests were performed to make sure that stimulation could never occur at restricted levels.

• The possibility of data corruption to important parameters was evaluated to make sure that the recipient would not be exposed to unsafe conditions, even in the case of data corruption.

All other functionality that did not raise any user- or safety-issues was not tested through extensive protocols. This was tested exploratory during and mainly after the implementation had been finalised.

The implementation phase was completed by September 2003. The complete PCIMAR system passed all verification activities completely on December 10, 2003.

The final permission to start with the clinical feasibility trial was given by Cochlear’s research and senior management was given on January 21, 2004.
5 PCIMAR Feasibility Clinical Trial

5.1 DESCRIPTION

The PCIMAR feasibility clinical trial is a single-centre, prospective and non-randomized clinical trial with sequential enrolment of all qualified subjects and is conducted under a MEC (medical ethical committee) approved clinical investigation plan.

5.1.1 Study objectives

The primary objective of the PCIMAR feasibility clinical trial is to demonstrate the feasibility of providing recipients the necessary controls to change their own speech processor mapping using the parametric fitting method as proposed by Smoorenburg.

Furthermore, the feasibility clinical trial will try to answer the following questions:

1) What are the resulting differences in MAP settings between the audiologist’s MAP and the recipient’s self-fitted MAP after a certain amount of time?

2) What are the resulting differences in speech understanding between both MAPs?

3) How great is the recipient’s subjective appreciation of the quality of the self-fitted MAP?

4) How great is the recipient’s subjective appreciation of the self-fitting procedure?

5) How many adjustments and time are needed by the recipient to find an optimal MAP?

In answering these questions, the performance of the PCIMAR technology will be quantitatively judged by the following measurements:

1) Speech scores in quiet and in noise, after a period during which the recipient has had the ability to change their own MAP, starting with the MAP as made by the audiologist. These speech scores will be obtained using CVC² and Sentences-in-Noise testing.

2) The amount of time that is needed by the recipient to create their preferred MAP, starting with the MAP as made by the audiologist.

The subjective appreciation of the quality of the self-fitted MAP and the self-fitting procedure will be assessed using a small questionnaire as listed in Appendix C.

² The Dutch CVC is a monosyllabic word test that is equivalent to the English CNC test.
5.1.2 Study layout
Each recipient that participates in the PCIMAR feasibility clinical trial will engage in four visits, in a pre-defined order. During each visit, speech scores will be obtained in quiet and in noise. During the final visit, a small questionnaire will also be filled in.

The speech tests will not only be performed with the MAP that was used during the previous phase. The original (traditionally fitted) MAP will also be tested each visit so that any kind of adaptation of the subject to the tests can be excluded when analysing the data.

5.1.2.1 PCIMAR Phase 1
The subjects receive a L34 speech processor with no PCIMAR functionality enabled. His/her existing MAP(s) are copied exactly into the new speech processor and the subjects return home for the next two weeks.

These two weeks will give the subjects a reasonable amount of time to adjust to the new speech processor. The adjustment period is necessary because research has shown that the auditory experience varies between different speech processors because microphone, analog front-end and filterbanks might differ. Variances in PCIMAR speech test scores as a result of the use of different speech processors will therefore be minimized.

5.1.2.2 PCIMAR Phase 2
The subjects return to the clinic after two weeks for continuation of the trial. A consonant-vocal-consonant (CVC) word test is performed at 55 and 65 dB SPL. Also, sentences-in-noise tests are performed with 70 dB speech and noise levels of 55 and 60 dB.

Before a new MAP can be fitted, the T-NRT values across the electrode array will be measured: these values will serve as the basis for an NRT-based MAP. Using Smoorenburg’s parametric fitting strategy approach, a parametric MAP is fitted for the subjects using as well shift and tilt modifications. During this visit, the audiologist also measures the subject’s LAPL values across the electrode array. The resulting MAP is copied to the speech processor and the subjects return home for the next three weeks.

PCIMAR functionality will still remain disabled. As research has shown that recipients perceive a different auditory experience with a newly parametrically fitted MAP, the subjects are given a period of three weeks in which they can grow accustomed to the new sound of the parametrically fitted MAP. By disabling PCIMAR during these first three weeks, variances in PCIMAR speech test scores as a result of this new MAP will be minimized.

5.1.2.3 PCIMAR Phase 3
The subjects once again return to the clinic for continuation of the trial after three weeks. During this visit, the subjects will receive access to the PCIMAR controls of the modified L34 speech processor. Initially, the CVC and speech-in-noise tests are repeated for both the 'old' and the 'parametric' MAP.
Before these controls are activated, the previously obtained LAPL levels are stored in one or more MAPs, with which voltage compliance telemetry measurements will be performed. This will make sure that the implant can deliver enough current for each possible PCIMAR modification that the subject may choose. If no problems are found, the MAP is updated with the proper LAPL values and the PCIMAR functionality will become available.

The subjects can then return home for the final three weeks in which MAP parameters can be modified through tilt and shift adjustments on both the T- and C-levels.

5.1.2.4 PCIMAR Phase 4

The subjects return to the clinic for the final time after another three weeks. During this final visit, the PCIMAR history log will be read from the speech processor for further analysis. The CVC and speech-in-noise tests are repeated for the 'old' and the 'PCIMAR' MAP. Finally, a small questionnaire (appendix C) will be filled out to assess the qualitative appreciation of the study and the results.

5.1.3 Determining LAPL values

As explained in 4.5.3, caution must be taken when providing recipients control over their map parameters. We’ve shown that there is only one way to completely prevent overstimulation by programming the speech processor with the absolute maximum stimulation levels, which are called the loudest acceptable presentation levels, or short: LAPL.

These LAPL values can not be determined by stimulating single electrodes at a time. The loudness summation effects that occur because of spatial and temporal summation due to electrical stimulation by adjacent electrodes would then not be accounted for. Determining the LAPL values is therefore always done while running a speech processing strategy using all electrodes (live mode), preferably while using wide-band stimulation e.g. white noise. Care must be taken while performing these measurements as the auditory perception by the recipient can quickly change from normal to unbearable loud or even painful!

The LAPL measurements are done by talking loudly while making other loud sounds, such as clapping. It is not explicitly necessary to use white noise as other loud sounds will also result in C-level stimulation at sufficient electrodes.

In the PCIMAR trial, the LAPL values are obtained as follows (see also Figure 50):

1) The audiologist first creates a MAP according to Smoorenburg’s parametric fitting theorem. The C-Levels of this MAP will in this chapter be referred to as the LAPL1 profile.

2) While in live mode, the LAPL1 profile is shifted (non-linearly) upward until the auditory perception becomes almost unbearable. Stimulation is immediately stopped and the MAP is saved. This MAP will be referred to as the LAPL2 profile.

3) The LAPL1 is now restored and tilted non-linearly by 1 standard-deviation. Again, in live mode, the profile is shifted (non-linearly) until the auditory
perception becomes almost unbearable. Stimulation is immediately stopped and the MAP is saved. This profile will be referred to as the LAPL3.

4) The procedure as mentioned in step 3 is repeated, but now, the LAPL1 profile is tilted non-linearly in the opposite direction. The resulting profile will be referred to as LAPL4.

5) Finally, the complete LAPL profile (LAPL5) is obtained by combining profiles LAPL2, 3 and 4. For each electrode, the LAPL value of this electrode is equal to the highest level on each of the three LAPL profiles.

![LAPL profile estimation](image)

**Figure 52 - LAPL profile estimation**

5.2 EXECUTION
The PCIMAR feasibility trial was performed with four subjects. Because only two L34 speech processors were available, the trial was split up into two study groups of two subjects each group 1: subject A & B, group 2: subject C & D. Table 2 shows some more information of the subjects. The inclusion criteria for participation in the trial were:

- Willingness to cooperate in the study
- Adult cochlear implant user with CI24M or Contour implant
- Full electrode insertion
- Using the ACE strategy preferably, otherwise SPEAK
- At least 5 months experience with their implant to ensure a stable MAP
- Native Dutch speaker
- No prior participation in any other kind of clinical trial involving parametric fitting strategies
Chapter 5 – PCIMAR Feasibility Clinical Trial

Table 2 – Subject details

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age</th>
<th>Deaf period</th>
<th>Cause of Deafness</th>
<th>CI Location</th>
<th>CI Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>M</td>
<td>71</td>
<td>34 years</td>
<td>unknown</td>
<td>Right</td>
<td>± 1.5 years</td>
</tr>
<tr>
<td>B</td>
<td>F</td>
<td>71</td>
<td>unknown</td>
<td>unknown</td>
<td>Right</td>
<td>± 1.5 years</td>
</tr>
<tr>
<td>C</td>
<td>M</td>
<td>42</td>
<td>8 years</td>
<td>Cogan</td>
<td>Right</td>
<td>± 1 year</td>
</tr>
<tr>
<td>D</td>
<td>F</td>
<td>80</td>
<td>unknown</td>
<td>Hereditary</td>
<td>Right</td>
<td>± 1.5 years</td>
</tr>
</tbody>
</table>

All subjects finished the complete trial schedule. The dates on which the subjects attended the clinic are mentioned in Table 3. Any protocol deviations will be addressed in the following sections.

Table 3 – Subject clinical visit dates

<table>
<thead>
<tr>
<th>Subject</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>February 17, 2004</td>
<td>March 9, 2004</td>
<td>March 30, 2004</td>
<td>April 27, 2004</td>
</tr>
<tr>
<td>D</td>
<td>February 17, 2004</td>
<td>March 2, 2004</td>
<td>March 23, 2004</td>
<td>June 1, 2004</td>
</tr>
</tbody>
</table>

5.2.1 Group 1
During the first visit of subjects A and B, it turned out that subject B frequently switched between two MAP settings in her BTE speech processor as she used one program for daily life and another program for telephone use. It was therefore decided to program this L34 speech processor with both MAPs.

We were unable to measure T-NRT levels for subject A. For his NRT-based MAP, we used his traditionally determined T-level profile as the basis. This is acceptable, since this study primarily aims to show the feasibility of (limited) self-fitting and does not attempt to prove the concept of NRT based fitting.

There were no abnormalities during the third and final visit, although subject B experienced fatigue towards the end of the session, which meant that we were unable to obtain test scores with her conventional MAP at that day.

5.2.2 Group 2
No abnormalities occurred during the first visit of subjects C and D.

During her second visit, subject D experienced a ringing in her ears (tinnitus). This may have affected her test scores. No abnormalities were observed for subject C.

The third visit of subjects C and D did also not pose any problems.

During the final stage, it became clear that the recipients were not able to cope well with the PCIMAR controls. Recipient C had trouble finding an optimal map. Recipient D did not notice the minus sign in front of the adjustment values and had
trouble understanding why a “+6” setting sounded different from a “-6” setting. They were both asked to return to the clinic after two weeks (April 13, 2004 and April 20, 2004 respectively). They were again instructed how to properly use the PCIMAR menu. With the consent of both the subjects and the audiologist, it was decided to extend the trial with 1 to 2 weeks.

Subject D finally returned to the clinic after the extended period. No additional problems were experienced during her final visit. Subject C was not able to return to the clinic on several occasions and finally returned after several weeks. During the final visit and after analysing the data, it became clear that this subject did not use his L34 speech processor on a regular basis. The results of this subject should therefore be treated with caution because probably no habituation to the PCIMAR adjustments has been established.

5.3 RESULTS
This chapter will show the outcomes of the feasibility clinical. In total, 4 subjects took part. Their CVC word and Sentences-in-Noise scores will be shown along with the course of their MAP adjustments. We will also point out the differences between their conventional MAP (MAP 0), the NRT-based MAP according to Smoorenburg’s fitting procedure (MAP 1) and the self-adjusted MAP (MAP 2). When comparing test scores for different MAPs, we will regard a MAP significantly better if the test score has increased by more than 10% when compared to the score of another MAP. This is a commonly used guiding principal in the field of cochlear implant research.

MAP 0 was measured three times: after adjusting to the new speech processor (measurement 1), after using the NRT-based MAP 1 (measurement 2) and after using the self-adjusted MAP 2 (measurements 3).

5.3.1 CVC Word Scores
The CVC word tests were performed at intensities of 55 dB and 65 dB. The results are shown below.

![Figure 53 - CVC Test Results at 55 dB](image-url)
When performing the CVC tests at 55 dB, two subjects (B and D) show a significantly increased test score for MAP 2 when compared to MAP 1. During the same visit, both subjects also show an increased performance for MAP 2 when compared to MAP 0. However, only subject D shows a better score for MAP 2 compared to MAP 0 at any visit. Subject A showed an increase in test score for MAP 2 when compared to MAP 0, but without improvement when compared to MAP 1. Subject C did not show an increase in performance at all.

For CVC testing at 65 dB, subjects A and D show about the same score for MAP 2 when compared to MAP 1. Subject B shows an improvement while subject C again shows a decrease in performance in this area.

When comparing MAP 2 to MAP 0, subject C shows no improvement, while all other subjects do. Subjects A and D show an improved score for MAP 2 when compared to MAP 0 at any visit. This is not apparent for subject B, however there is a significant improvement in performance for MAP 2 over MAP 0 during the same visit.
5.3.2 Sentences-in-Noise Scores

The Sentences-in-Noise tests were performed with 75 dB speech and noise intensities of 55 dB and 60 dB. The results are shown below.

![Sentences-in-Noise Test Results (Noise level 55 dB)](image)

These results are rather erratic. Subject A peaks with a good score for MAP 0 during his first visit. For subsequent visits, the scores gradually increase with MAP 2 scoring about the same as MAP 1, but better than MAP 0 when not taking into account the first measurement of MAP 0.

Subject B shows a degrading performance for MAP 2 and MAP 1 when compared to MAP 0. We were unable to measure MAP 0 during her final visit as testing had completely worn her out by that time.

Subject C also shows abnormal test scores. Specifically the test scores during the second visit are very bad compared to the scores that were obtained during the other visits. The test scores that were obtained during the final visit are very large. However, the score for MAP 2 is significantly lower when compared to MAP 0. It would seem that the results show a strong time-dependent variability.

Subject D shows a low score for MAP 0 during her first visit. The scores for MAP 0 and MAP 1 during her second visit are lower, however one should consider that she was at that time troubled by a ringing in her ears (tinnitus), which probably affected her scores. Although MAP 2 shows a higher score, the result for MAP 0 was much better at that time.
The testing of sentences at 60 dB noise levels proved extremely difficult with some subjects. Only subjects A and C could perform this test. Subject A scored better using MAP 2 when compared to MAP 1. Although the score for MAP 2 is larger than for MAP 0 during the same visit, no significant improvement can be seen when compared to the scores for MAP 0 at any visit. Subject C again shows very low scores during his second visit. The score for MAP 2 is significantly better than MAP 0 during any visit.

5.3.3 PCIMAR Adjustments
Appendix D.5 shows the total number of adjustments that have been performed over the entire period that the subjects had PCIMAR controls on their speech processor activated. Each adjustment is accounted for, which means that increasing a tilt variable from 0 to 4 equals 4 adjustments.

The number of adjustments on each day have been normalised to the total adjustments that were performed during the entire trial. This has been done because the total amount of adjustments varied strongly between roughly 150 adjustments by subject A to about 3800 adjustments by subject C.

The plots show that subjects A and B performed the majority of adjustments after about two weeks. Subject D performed the most modifications after one week, both during the first and second part of the final phase as she was recalled to the clinic after two weeks, at which point it was decided to extend the trial with an extra week. At the end of the final phase of the trial, no subject showed the need to adjust the parameter settings. The results for subject C should be disregarded, because this subject did not use his speech processor on a regular basis.

Appendix D.1 through D.3 show the individual adjustments for the shift and tilt parameters of the T- and C-level profiles. For subject A, both the shift and tilt parameters gradually stabilise at a fixed value for both the T- and C-level profiles. It should be noted that very few adjustments were made to the T-level profile.
The adjustments of subject B show that she tried a lot of different settings to find an optimal MAP. Although the plots show the C-level shift and tilt parameters stabilise, this remains indecisive for the T-level shift and tilt parameters as they show strong variations towards the end of the test period. Subject B performed relatively few adjustments to the T-level profile.

Finally, the parameters of subject D stabilise rather quickly when taking into account that this subject did not notice the minus sign during the first part of the final test phase. After this was explained again, the parameters quickly return to the stable setting that the subject already found during the first part of the test phase. Subject D also performed almost no modifications to the T-level profile.

### 5.3.4 MAP comparisons

The plots in Appendix E: show the conventional MAPs, the parametric MAPs as created by the clinician according to Smoorenburg’s parametric fitting strategy for each recipient and the self-adjusted MAPs as created by the recipients. The differences between the various MAPs will be addressed below.

#### 5.3.4.1 Subject A

Subject A did not adjust the C-level profile completely up to the LAPL levels. His adjustments created a MAP with more basal stimulation while keeping the apical stimulation levels rather consistent. The new T-level shows a MAP which is more sensitive for basal stimulation.

When comparing the self-adjusted MAP 2 with the conventional MAP 0, MAP 2 also shows more basal stimulation. Because of the parametrically fitted basic MAP 1, the T-level profile is greatly decreased.

#### 5.3.4.2 Subject B

The plots clearly show that subject B had very little room to adjust her C-level profile, because of the tightly determined LAPL values. Subject B explained during the final test session that she would have liked to increase her C-level further but was unable to do so. Unfortunately, she did not mention this during the final stage, in which case the clinician could have considered adjustments to the LAPL values. The C-level profile of MAP 2 shows somewhat more basal stimulation as well as increased apical stimulation. The T-level profile shows a decreased basal and increased apical stimulation threshold value.

Comparing MAP 2 with MAP 0, almost no differences are noticeable. Because of the parametric fitting, MAP 2 shows a lowered T-level profile, especially for the basal electrodes.

#### 5.3.4.3 Subject C

Subject C shows the largest amount of headroom to adjust his C-level profile. Unfortunately, this subject did not use the speech processor on a regular basis, so no habituation to the new settings could develop. This would explain why this subject only increased his C-levels only slightly when compared to the measured LAPL values.
When compared to MAP 0, MAP 2 shows an overall increase in the C-level profile. The T-level profile has decreased.

5.3.4.4 Subject D
Subject D had very little room to adjust the C-level profile. The adjustments show an increase in basal stimulation. The T-level has remained almost unchanged.

A comparison of MAP 2 with MAP 0 shows almost no differences for the C-level profile, however a slight increase in basal stimulation can be seen. Again, the T-level profile is decreased.

5.3.5 Questionnaire
The questionnaire revealed that subject A preferred the PCIMAR MAP, as did subject B who indicated that her own adjustments sounded more “clear” in her head. Subject C indicated his own MAP sounded somewhat ‘wobbly’, but enjoyed it in noisy situations. When using the phone, subject C indicated his own adjustment as very bad. Overall, subject C preferred his own MAP. Subject D was not happy with her own adjustment and preferred her old MAP. She also indicated that there were too many variable parameters, which confused her.

Subject A showed the most appreciation for the PCIMAR controls. He believes it is a good method to obtain an optimal MAP, but the functionality should only be available for a short period of time. Otherwise, he believes that people will keep on adjusting endlessly without trying to adapt to certain MAP settings that approach the optimum. On request, the PCIMAR MAP was programmed in the regular speech processor of subject A.

Subject B was somewhat less enthusiastic, although she generally liked the idea to perform adjustments. She agreed with subject A that adjustments should however not be available all the time. Subject A also wanted the PCIMAR MAP to be programmed in her regular speech processor.

Subject C experienced the self-control over MAP parameters as annoying, however he also expressed that recipients are able to find a better setting than the clinician. Although not completely satisfied with the performance of his self-made MAP, subject C also requested this MAP to be programmed in his regular speech processor. He confirmed that he did not use the L34 speech processor very often and now believes that with more time to adjust to the MAP, he will enjoy it more, which supports our view that his test scores should be treated with reservations.

Subject D indicated that MAP adjustments should not be performed by recipients. She got confused by the controls and believes a trained person can make better judgements.

When calling subjects A and B about 5 weeks after their final visit, they still used their own MAP and did not plan on reverting back to their conventionally fitted MAP.
6 Discussion

The major results of the present study are as follows and will be discussed in more detail below.

1) The PCIMAR adjustments overall resulted in more basal stimulation for subjects A and D and less basal stimulation for subject B. Subject B showed a clear drop in performance in noise which could be related to the basal stimulation pattern.

2) There were no significant differences between the PCIMAR and conventional MAPs or parametric MAPs in this small population. There seems to be a trend towards better speech scores with the PCIMAR MAPs compared to the conventional MAPs, although previous test scores for the conventional MAPs lead us to a different conclusion.

3) Although two recipients expressed a large subjective appreciation for their self-adjusted MAP, no clear conclusion regarding the objective performance can be drawn out of the present data. It is possible that the modifications only lead to a subjectively better audio-quality but not result in a better understanding of speech.

4) The subjective appreciation for control over their MAP parameters was rated high by most recipients.

5) The recipients did not become at drift in their MAP modifications. The adjustment parameters tend to stabilise to a certain value within a limited amount of time (about 1 to 2 weeks). The total number of adjustments varied greatly among subjects.

6.1 QUANTATIVE RESULTS

For the limited number of four subjects, the present study showed that the self-adjusted MAP might increase speech reception compared to the conventional MAP. No decreases in effectiveness were observed, except for the CVC tests of subject C and the sentences-in-noise scores of subjects C and D at a 55 dB noise level.

Subject A scores better with the self-adjusted MAP than with his conventional adjustment, although the first test scores of the conventional adjustment remain the highest for sentences-in-noise testing.

Subject B also shows better CVC test results when using MAP 2 compared to MAP 0 at the same visit; however this is not apparent for previous measurements of MAP 0. Her performance with MAP 2 for sentences-in-noise testing is quite bad compared to the scores of MAP 0.

Subject C again shows some unexplained results as his overall test scores for MAP 2 are worse compared to the scores of MAP 0. However, the more difficult sentences-in-noise test with 60 dB noise shows a clearly increased score.
Subject D shows the opposite result, as her self-adjusted MAP performs worse when compared to the conventional MAP score at the same day. However, her self-adjusted MAP score is higher than the first measurement of the conventional MAP. The results of subject D remain inconclusive on this point.

The self-adjusted MAPs also show a slight increased performance when compared to the NRT-based MAP. This is apparent from the CVC test scores: apart from the CVC tests of subject A and C, all other CVC tests showed equal or better results when using the self-adjusted MAP. Even the 55 dB CVC test scores of subject A are almost similar. The sentences-in-noise tests also show improved results for the self-adjusted MAP when compared to the NRT-based MAP. The only exception is subject B, however we must consider that she showed signs of fatigue during testing. Subject C shows rather puzzling results: although the CVC test scores all decrease for the self-adjusted MAP compared to the NRT-based MAP, the sentences-in-noise scores increase dramatically, which is something that we can not explain.

These results might therefore point out that the PCIMAR functionality is able to help create a qualitatively better MAP, when no fine-tuning has been performed at the clinic. However, it also shows that for these subjects, the PCIMAR functionality does not necessarily produce a qualitatively better MAP than the conventionally fitted MAP that already has been fine-tuned over a far more extended period of time.

6.2 MAP MODIFICATIONS
The results of this study show that the available period of three weeks is adequate for all subjects to find an optimal setting for their MAP. Quite importantly, none of the subjects got lost in their MAP modifications. All subjects ended up with a stable C-level profile shift and tilt setting. The results of the T-level profile settings remain somewhat inconclusive, mainly because of subject B. Subjects A and D ended up with stable settings for the T-level profile. The resulting MAPs showed more basal stimulation, with fairly unchanged apical stimulation.

Interestingly enough, very few modifications were performed to the T-level profile. The question arises whether the recipients were always aware that they could perform modifications to their stimulation threshold settings, or that the adjustments to the T-level profile do not produce any immediately noticeable results. In that case however, one would expect to see subjects increasing the T-level parameters to the absolute maximum settings (± 19), which is something that only occurred with subject C.

6.3 SUBJECTIVE APPRECIATION
The subjective appreciation of the PCIMAR functionality was high, especially with subjects A and B. Subject D also appreciated the functionality however; she was overwhelmed by the amount of controls presented. Although the volume control functionality of the speech processor was disabled, the PCIMAR functionality offered four new controls. The sensitivity control (3.4.1) was also still present. In combination with the new speech processor, this might have been too much to adjust to.

Subjects A, B and C requested that their self-adjusted MAP was programmed (in additional to their conventional MAP) in their own BTE speech processor at the end of the trial. A follow-up telephone call after five weeks with subjects A and B revealed that both subjects still used their self-adjusted MAP.
Chapter 7 – Conclusion and recommendations

7 Conclusion and recommendations

The study successfully addressed the objectives we set out to achieve. We analysed the differences between the conventionally fitted, NRT-based and self-adjusted PCIMAR MAP. We identified varying speech scores and experienced various levels of subjective appreciation towards the quality of the MAPs. We also showed that the subjects could find an optimal setting within a limited period of time, although the number of adjustments can vary significantly.

Note that this small feasibility study was only a pilot project. An extended study, possibly multi-centred, would have to be performed before any statistically justified findings can be presented. This is mainly the reason why no quantitative statistical analysis is given for the different speech test scores.

The final results remain somewhat inconclusive. Although we showed that the self-adjusted MAP overall performs better with most recipients, previous measurements that were performed with the conventional MAP (with which the recipients had at least one year experience) lead us to a different conclusion. We also showed that the PCIMAR functionality might increase the effectiveness of the NRT-based MAP.

What is encouraging is that the self-adjusted MAP did not show largely decreased scores compared to the conventionally fitted MAP. Taking into account the extensive experience with the conventional MAP, it can be argued that the PCIMAR functionality enhances the NRT-based fitting strategy and leads to a qualitatively good MAP within a much smaller time-frame than is needed with the conventional fitting strategy. Of course, to really prove this statement, an experiment with naïve users that did not already get a conventional MAP should be performed. Preferably a crossover trial with randomised treatment order would then be used.

The procedure that was used to determine the LAPL values for the electrode array proved to be effective, yet time-consuming. None of the subjects complained that they could adjust their MAP settings to excessively loud settings, which would be considered as over-stimulation. Possibly this means that the LAPL values may have been set too conservatively, which is also expressed by the fact that subject B actually wanted more headroom for C-level adjustments.

Should future studies be based on this project, we would advise a strong reduction of the possible variable settings. Although volume control was disabled, the analysis of the adjustments showed that very few adjustments were made to the T-level shift and tilt settings. Because the subjects felt overwhelmed with possible adjustment parameters, we hypothesize that most of the time, they were not even aware that they were adjusting their threshold stimulation settings. Another possibility is that they tried, but simply did not notice large effects by these adjustments. Our suggestion would be to disable T-level modification and focus on C-level modifications completely, or at least have both adjusted sequentially rather than simultaneously.

Although the adjustment range of two standard deviations positive and negative showed to be sufficient, it might also be wise not to use positive and negative values for the parametric settings. Although this makes sense to engineers and researchers...
who are aware of the origins of this adjustment range, some subjects found it difficult to cope with the negative values.

Finally, it might be a good idea to disable the recipient’s sensitivity control as well by replacing it with auto-sensitivity control to reduce the possible variables even further.

The results of the present study suggest the following future research possibilities:

- **Provide PCIMAR control for subjects with already advanced conventionally fitted MAPs**

  The idea for this research is based on the relatively good results that were obtained with subject A, with whom we could not obtain proper NRT results and therefore opted to use his T-level profile as the basis for MAP 1.

  This research should determine if recipients can further increase the effectiveness of their conventionally fitted MAP by fine-tuning the parameters outside the clinic.

- **Provide PCIMAR control immediately for new cochlear implant recipients**

  This research has shown that recipients are able to modify their MAP themselves without creating a qualitatively bad MAP. We have also shown that PCIMAR enhances the NRT-based MAP. However, the study has been performed with recipients who already had extensive experience with their cochlear implant and were all this time used to their conventionally fitted MAP. One might wonder if an NRT-based MAP together with PCIMAR controls provides equally good or better results when recipients are fitted this way right from the start.

  In this case, a balanced cross-over study would have to be performed. In this study, one group of new cochlear implant recipients are fitted with a basic NRT-based MAP and receive a L34 speech processor with PCIMAR controls with which they can adjust their settings. At the end of a certain period, they would be fitted with a conventional MAP. The other group would perform the same procedure, but start off with the conventionally fitted MAP. This research should initially be guided very closely by an audiologist, because the LAPL values need to be determined carefully and adjusted more frequently.
8 Epilogue

The master thesis project at Cochlear was probably the most intense learning experience of my entire curriculum. The diversity of the tasks posed the biggest challenge. PCIMAR wasn’t a regular project in which the tasks were well defined. Rather, this time I had to learn how to set-up and participate in managing an entire medium-scale project.

The project management had to take into account the work schedules of different employees at the Cochlear Technology Centre (Mechelen) and Cochlear Limited (Sydney) because support needed to be provided during development and for reviewing the necessary design and verification documentation. Although the project was planned to be completed within 9 months, delays were introduced by minor design flaws but most of all because the necessary L34 speech processor systems for the clinical feasibility trial were not available on time.

Writing all the internal documentation at Cochlear taught me how to properly follow Cochlear’s Design Control Process and how to write technical documents for a variety of readers.

The implementation of the firmware was done in assembly language. Although I already had 8051 assembly knowledge, the analog devices DSP assembly code was unknown to me at the beginning. The DSP code proved to be easy to learn and very powerful at performing difficult calculations, which was very helpful for the MAP recalculation routines. On top of that, I was fortunate enough to have basic programming knowledge for writing Windows utilities in Visual C++.

The feasibility clinical trial itself was probably the most exciting part of the project and well worth the wait. Not only did I finally see the results of all the hard work: the study put me right in the middle of audiological research, which was a very valuable experience. Although I had already met some recipients and had wonderful conversations, it was a fantastic experience to work with a few of them. The level at which these people can communicate is unbelievable. It’s a wonderful feeling of being able to participate in the work that enables people to hear again: the clinical trial put me right in the middle of it.
## Chapter 9 – Terms, definitions and abbreviations

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<td>ABR</td>
<td>Auditory Brainstem Response</td>
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<tr>
<td>ACE</td>
<td>Advanced Combination Encoder (speech processing strategy)</td>
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<td>BTE</td>
<td>Behind-The-Ear (part of the) speech processor</td>
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<tr>
<td>C-level</td>
<td>Comfortable maximum stimulation level</td>
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<tr>
<td>CIS</td>
<td>Continuous Interleaved Sampling (speech processing strategy)</td>
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<tr>
<td>CLTD</td>
<td>Cochlear Limited (Sydney – Australia)</td>
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<tr>
<td>CSLI</td>
<td>CIP Script Language Interpreter (Cochlear internal tool)</td>
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<tr>
<td>CTC</td>
<td>Cochlear Technology Centre (Mechelen – Belgium)</td>
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<tr>
<td>CVC</td>
<td>Consonant-Vocal-Consonant, audiological Dutch word test and the equivalent to the English CNC test</td>
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<tr>
<td>DSP</td>
<td>Digital Signal Processing</td>
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<td>EABR</td>
<td>Electrically-evoked Auditory Brainstem Response</td>
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<tr>
<td>ECAP</td>
<td>Electrically-evoked Compound Action Potential</td>
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<tr>
<td>GUI</td>
<td>Graphical User Interface</td>
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<tr>
<td>Headset</td>
<td>Combination of BTE and coil</td>
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<tr>
<td>LAPL</td>
<td>Loudest Acceptable Presentation Level</td>
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<td>Live mode</td>
<td>Process of activating the entire speech processing on a speech processor according to a downloaded MAP while monitoring the stimulation using the programming software.</td>
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<tr>
<td>L34SP</td>
<td>Laura34 speech processor</td>
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<td>MAP</td>
<td>A set of parameter values for electrical stimulation, specific for an individual recipient.</td>
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<tr>
<td>NPE</td>
<td>Nucleus Programming Environment (fitting software)</td>
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<td>NRT</td>
<td>Neural Response Telemetry</td>
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<td>R126</td>
<td>Cochlear’s commercial fitting software</td>
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<td>PCA</td>
<td>Principal Component Analysis</td>
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<td>PCIMAR</td>
<td>Parametric Cochlear MAP Adjustment by Recipients (project name)</td>
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<td>SP</td>
<td>Speech Processor</td>
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<td>T-level</td>
<td>Threshold stimulation level</td>
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Chapter 10 – References

10 References

10.1 BOOKS

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SUMMARY OF RESULTS USING THE NUCLEUS CI24M IMPLANT TO RECORD THE ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL.

INTRAOPERATIVE AND POSTOPERATIVE ELECTRICALLY EVOKED AUDITORY BRAIN STEM RESPONSES IN NUCLEUS COCHLEAR IMPLANT USERS: IMPLICATIONS FOR THE FITTING PROCESS.

THE RELATIONSHIP BETWEEN EAP AND EABR THRESHOLDS AND LEVELS USED TO PROGRAM THE NUCLEUS24 SPEECH PROCESSOR: DATA FROM ADULTS.
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RATE AND TIMING CUES ASSOCIATED WITH THE COCHLEAR AMPLIFIER: LEVEL DISCRIMINATION BASED ON MONOAURAL CROSS-FREQUENCY COINCIDENCE DETECTION

COMPARISON OF EAP THRESHOLDS WITH MAP IN THE NUCLEUS24 COCHLEAR IMPLANT: DATA FROM CHILDREN.

A SIMPLE TWO-COMPONENT MODEL OF THE ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL VIA A NEURAL RESPONSE TELEMETRY SYSTEM.

REVIEW OF THE ROLES OF TEMPORAL AND PLACE CODING OF FREQUENCY IN SPEECH DISCRIMINATION.

[16] Moore, B.C.J.
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[17] Smoorenburg, G.F. and C. Willeboer, J.E. van Dijk
SPEECH PERCEPTION IN NUCLEUS CI24M COCHLEAR IMPLANT USERS WITH PROCESSOR SETTINGS BASED ON ELECTRICALLY EVOKED COMPOUND ACTION POTENTIAL THRESHOLDS.
APPENDIX A: COMPANIES & INSTITUTES

A.1 Cochlear
Cochlear Limited develops and produces cochlear implant devices for individuals with severe to profound hearing loss. The company was formed in 1982 to build on the work of Australian Professor Graeme Clark, the inventor of the multi-channel cochlear implant. Today, Cochlear sells its Nucleus cochlear implant systems in more than 70 countries, supporting over 50,000 recipients that have been implanted with Nucleus hearing implants.

Cochlear’s most advanced commercial implant system is the Nucleus 3 system, comprising of the Esprit 3G BTE speech processor and an implant of the Nucleus 24 series. The Esprit 3G BTE supports various speech-coding strategies, e.g. CIS and ACE. The Nucleus 24 implants offer 22 intracochlear and 2 extracochlear electrodes as well as NRT support. Part of the Nucleus 24 implant series is the Nucleus 24 Contour, which is a self-curving electrode for safely inserting the electrode array closer to the inner wall of the cochlea. These implant systems are configured with Cochlear’s R126 fitting and NRT software.

The Cochlear Technology Centre Europe is located in Mechelen (Belgium). It is part of Cochlear’s research environment and employs 38 people, most of which are engineers and researchers. The design of the PCIMAR project has been performed at this facility.

A.2 University Medical Centre Utrecht
The University Medical Centre Utrecht exists under this name since 1999 and consists of three locations: the Academic Hospital Utrecht, the Wilhelmina Children’s Hospital and the Medical Faculty Utrecht.

The Hearing Research Laboratory is led by Prof. Dr. Guido F. Smoorenburg. The PCIMAR feasibility clinical trial has been performed at this institution.
# Appendix

**APPENDIX B: PCIMAR COEFFICIENTS**

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APPENDIX C: PCIMAR QUESTIONNAIRE

1. Inleiding
U heeft meegedaan aan het onderzoek voor de afregelbare processor. Dit onderzoek bestond uit 3 periodes:

1) In de eerste periode heeft u de L34 processor gebruikt met uw oorspronkelijke instelling.
2) In de tweede periode heeft u de L34 processor gebruikt met een nieuwe instelling gebaseerd op de metingen die tijdens de operatie gedaan zijn.
3) In de derde periode heeft u de L34 processor gebruikt en kon u zelf wijzingen aanbrengen in de instelling.

In deze vragenlijst staan een aantal vragen over de afregelbare processor. We willen geen informatie krijgen over de processor zelf (zoals spoel, microfoon etc) maar alleen over de afregelmogelijkheden. Kruis steeds het antwoord aan wat het meest van toepassing is. Meestal kunt u maar één antwoord kiezen. Soms ook meerdere, in dat geval staat het erbij.

2. Over de kwaliteit van de instellingen
Deze vragen gaan alleen over de geluidskwaliteit van de verschillende instellingen.

Welke instelling vindt u op dit moment het meest aangenaam?
☐ Mijn oorspronkelijke instelling (periode 1).
☐ De instelling van periode 2, die gebaseerd was op de metingen tijdens de operatie.
☐ De instelling die ik zelf gemaakt heb in periode 3.

Stel dat u alle drie de instellingen ter beschikking had. Hoe vaak zou u elke instelling gebruiken:
Mijn oorspronkelijke instelling (periode 1) ☐ Nooit ☐ Soms ☐ Altijd
De instelling uit periode 2 ☐ Nooit ☐ Soms ☐ Altijd
De zelfgemaakte instelling (3) ☐ Nooit ☐ Soms ☐ Altijd

Heeft u specifieke opmerkingen over de geluidskwaliteit van de verschillende instellingen (zoals: goed voor telefoon, slecht voor op feestjes, etc):
Over mijn oorspronkelijke instelling (periode 1):

Over de instelling van periode 2:

Over de zelfgemaakte instelling van periode 3:

Wilt u een kopie van de zelfgemaakte instelling in uw eigen processor?
☐ Ja, heel graag ☐ Ja ☐ Niet echt nodig.

Indien u een kopie van de zelfgemaakte instelling in uw eigen processor zou krijgen, hoe vaak zou u die dan gebruiken?
☐ Nooit ☐ Zelden ☐ Vaak ☐ Altijd

3. Over het zelf bijregelen van de instelling
Deze vragen gaan over of u het prettig vond om zelf bij te kunnen regelen. Ze gaan niet over het gebruiksgemak van de afregelbare processor (die vragen staan in deel 4).

Vond u het prettig om zelf de instellingen te kunnen bijregelen?
☐ Ja, heel prettig ☐ Niet prettig, niet onprettig ☐ Onprettig

Parametric Self-Fitting of Cochlear Implant Systems at Home Page 85
Waarom vond u het prettig of onprettig om zelf te kunnen bijregelen (kruis steeds 1 van de mogelijke antwoorden aan die het beste uw mening omschrijft):

☐ De geluidskwaliteit van mijn zelfgemaakte instelling is beter.
☐ De geluidskwaliteit van mijn zelfgemaakte instelling is niet beter.
☐ Het is prettig om in verschillende omstandigheden de instelling te kunnen bijregelen.
☐ Het is vervelend om steeds bij te regelen.
☐ Het zelf bij kunnen regelen geeft mij het gevoel dat ik zelf kan bepalen wat ik hoor en wat niet.
☐ Ik vond het zelf bijregelen onprettig omdat ik nooit zeker weet of ik de juiste instelling maak.
☐ Een audioloog kan beter bepalen wat de beste instelling is dan ik het zelf kan doen.
☐ Ik kan zelf beter bepalen wat de beste instelling is dan mijn audioloog, ik hoor het immers.
☐ Het is beter om thuis of op mijn werk de instelling te kunnen bepalen dan (alleen) in het ziekenhuis.
☐ Het is beter om de instelling te bepalen in het ziekenhuis, in een rustige kamer met een bekende stem.
☐ Het beste zou zijn als ik een tijdje zelf mijn instelling kan maken tot ik tevreden ben; daarna moet de instelling blijven zoals hij is.
☐ Het zou het beste zijn als ik altijd veranderingen in mijn instelling zou kunnen maken.
☐ Het zou het beste zijn als alleen / uitsluitend de audioloog de instelling voor mij zou maken.

Hoe vaak per dag veranderde u iets aan de instelling in de eerste dagen?

☐ HEEL VEEL ☐ VEEL ☐ WEINIG ☐ HEEL WEINIG

En op het einde van het experiment?

☐ HEEL VEEL ☐ VEEL ☐ WEINIG ☐ HEEL WEINIG

En hoe vaak denkt u dat u nog wijzigingen zou aanbrengen als u de processor een jaar mag gebruiken?

☐ HEEL VEEL ☐ VEEL ☐ WEINIG ☐ HEEL WEINIG

4. Het bedienen van de afregelbare processor

HET LEREN OM DE INSTELLING TE VERANDEREN WAS:

☐ HEEL MOEILIJK ☐ MOEILIJK ☐ MAKKELIJK ☐ HEEL MAKKELIJK

NU IK ERAAN GEWEND BEN IS HET VERANDEREN VAN MIJN INSTELLING:

☐ HEEL MOEILIJK ☐ MOEILIJK ☐ MAKKELIJK ☐ HEEL MAKKELIJK

DE HANDLEIDING WAS (MEERDERE ANTWOORDEN MOGELIJK):

☐ DUIDELIJK ☐ ONDUIDELIJK
☐ TE UITGEBREID ☐ TE BEKNOPT

EVENTUELE SUGGESTIES VOOR VERBETERINGEN:

5. Verdere opmerkingen

Hieronder kunt u verdere opmerkingen kwijt:

Bedankt voor uw medewerking.
APPENDIX D: PCIMAR ADJUSTMENTS OVER TIME

D.1 Subject A

![Graph showing PCIMAR adjustments over time for Subject A.](image-url)
D.2 Subject B

Appendix

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D.3 Subject C
D.4 Subject D

Appendix

Parametric Self-Fitting of Cochlear Implant Systems at Home
D.5 Total adjustments

Group 1

Total number of adjustments subject A = 149.
Total number of adjustments subject B = 3786.

Subject C

Total number of adjustments subject C = 596.
Total number of adjustments subject D = 375.
APPENDIX E: MAPS

E.1 Subject A

Smoorenburg's parametric MAP and self-adjusted MAP

Conventional MAP and self-adjusted MAP
E.2 Subject B

Smoorenburg's parametric MAP and self-adjusted MAP

Conventional MAP and self-adjusted MAP
E.3 Subject C

Smoorenburg’s parametric MAP and self-adjusted MAP

Conventional MAP and self-adjusted MAP
E.4 Subject D

Smoorenburg's parametric MAP and self-adjusted MAP

Conventional MAP and self-adjusted MAP