

CHALMERS



A stand-alone test device for Bone Conduction Implant (BCI)



Master of Science Thesis in Biomedical Engineering

Phase 2

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Abstract

Bone conduction hearing is when vibrations in the skull bone stimulate the cochlea and thereby lead to sound perception. Bone conduction hearing aids use this phenomenon to provide an alternative solution for patients with hearing impairment mainly in the outer ear or middle ear. A new Bone Conduction Implant (BCI), which has been designed and developed at Chalmers University of Technology and Sahlgrenska University Hospital, is an alternative to the percutaneous Bone Anchored Hearing Aid (BAHA) that is attached to the skull bone via a skin penetrating titanium screw. Although BAHA has been successful for three decades, the skin penetration requires a life-long daily care and may lead to complications such as skin infections or loss of implant. In the BCI, no skin penetration is required and the skin is kept intact. The BCI consists of an external sound processor with a transmitter coil to transmit the sound via an inductive link to a receiving coil in the implanted unit. Then, the sound signal is converted to the mechanical vibrations by a Balanced Electromagnetic Separation Transducer (BEST).

This project aims to develop methods for functionality testing of the BCI in situ. It is very important to detect a possible malfunctioning implant during surgery, and also to have methods to follow the implant performance over time and to make a quick performance verification test in situ.

The first phase of this project, which has been reported by Shirinkar and Ghoncheh (2013), was dealing with a non-invasive method using nasal sound pressure (NSP) to verify the functionality of BCI during surgery before the surgical incision is closed. The results clearly implied that the NSP method is suitable for the test and verification of the implanted part of the BCI. This was confirmed in the first surgery. The NSP method is also used in follow-up of patients to verify the functionality of the implanted unit of the BCI.

This report deals with the second phase of the project with the aim to develop a more simple battery operated stand-alone test device. Initially, different possible solutions for BCI verification were investigated based on an electrical signal driving the transmitter unit and by measuring the frequency response by a sound probe in ear canal or nasal cavities or acoustically emitting from the outer skin surface over the implant. Among different options to generate a proper signal for stimulation, it was decided to use pure tones because it produces familiar signals to human ear. It was found that the transmitted electrical signal to the implant can be heard in the surrounding environment as an aerial sound from the transducer vibrations that are emitting through the skin. As this is a simple and easy-to-do test it was decided to implement this in the battery operated BCI audio processor. Tones with different frequencies were generated using the pre-configured DSP (R3910 from ON semiconductor). To evaluate the efficiency of the test device, two listening tests were performed with different signals.

The conclusion is that the battery operated test device developed can be used by clinicians and doctors to verify implant performance both during surgery and post implant follow ups.

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List of abbreviations and acronyms:

AC	Air Conduction / Air Conducted
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction / Bone Conducted
BCI	Bone Conduction Implant
dB	deciBel
ECSP	Ear-Canal Sound Pressure
HL	Hearing Level
NSP	Nasal Sound Pressure
SPL	Sound Pressure Level
TM	Tympanic Membrane
DSP	Digital Signal Processing/Processor
BBC	Bridging Bone Conductor
MUX	Multiplexer
ADM	Adaptive Directional Microphones
AFC	Adaptive Feedback Cancellation
AGC	Automatic Gain Control
IDS	Intructive Data Sheet

1

Introduction

HEARING impairment is the most frequent sensory disorder in humans, affecting more than 360 million people in the world [1]. Communication, social and economic problems are only some aspects of this impairment. Receiving acoustic stimulation through the auditory system and converting it to auditory sensation will result in hearing. The acoustic stimuli received by the ears is converted into mechanical vibrations and generates cochlea stimuli, where neural impulses are produced. For auditory perception, two transmission pathways exist including air conduction and bone conduction. In air conduction hearing, an acoustic signal travels through the outer ear, middle ear and then arrives at the cochlea. Bone conduction is the pathway where an acoustic signal cause vibration within the skull bones and stimulates the cochlea. The conversion mechanism of mechanical vibrations into neural impulses, which occur in the cochlea, is the same for bone conduction and air conduction hearing [2].

People who suffer from conductive hearing loss cannot be treated by conventional hearing aid because, the sound does not reach the cochlea properly. However, using a bone conduction hearing aid would be a solution for these patients, to transmit the

sound data into the cochlea, bypassing the middle ear. Today, a percutaneous Bone Anchored Hearing Aid (BAHA) is an appropriate alternative for such patients, as well as patients with mixed hearing loss and single-sided deafness. Such a hearing aid has a percutaneous bone anchored implant with a snap coupling for the sound processor and bone conduction transducer. A microphone receives the sound and amplifies it. This amplified sound will be transmitted directly as vibrations within skull bone to the cochlea, by-passing the middle ear. BAHA has been successful for patients with a pure conductive deafness, mixed hearing loss and single-sided deafness. However, the skin penetration requires a life-long daily care and will sometimes cause infections. Some drawbacks have been reported, such as skin redness, skin infection and loss of implant (accidental or spontaneous) [3], [4], [5].

To overcome the aforementioned problems, the Bone Conduction Implant (BCI) has been designed at Chalmers University of Technology and Sahlgrenska University Hospital, by which no skin penetration is required and therefore the skin is kept intact [3].

The BCI system is divided into an external part, an implanted unit and an inductive link. The external part consists of a microphone, signal processor and tuned driver, which transmit the signal into the inductive link. The implanted unit, called the Bridging Bone Conductor (BBC) unit, includes transducer, receiving coil and demodulator (see figure 1.1) [6] citeDSRG:journalSabineBHM2013.

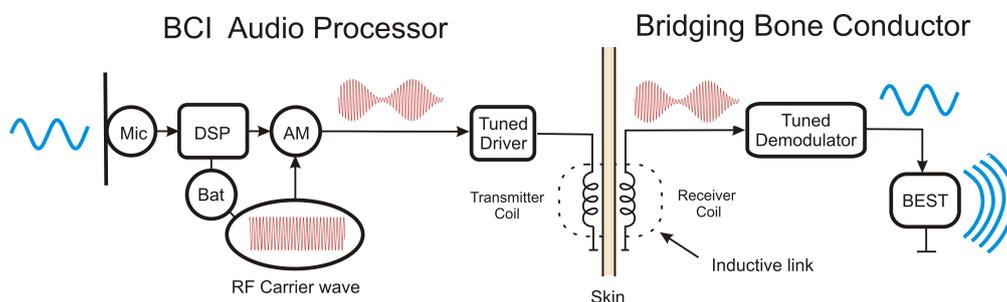


Figure 1.1: The block diagram of a BCI system [6].

Furthermore, the BCI transducer is positioned closer to the cochlea compared to a BAHA, which leads to an increased sensitivity to bone conducted sound that will compensate for the loss in the inductive link [3], [7].

The previous studies by Reinfeldt et al.[3], [8] showed that the sound pressure in the ear canal (ECSP) relates to BC hearing thresholds and therefore the sensitivity of the cochlea. The aim in Reinfeldt et al.[3] was to show the differences in sensitivity between stimulation at the BAHA and BCI positions.

By electrically stimulating the implant and measuring the ECSP, the functionality of the implant would be possible to determine. To measure the ECSP, a probe tube microphone can be used to detect sounds which are propagated in the skull in a three-dimensional manner. In Reinfeldt et al. [3], stimulation was given transcutaneously (through the skin) in 20 normal hearing subjects, showing that the BCI position, which is closer to the cochlea, gives higher sensitivity than the BAHA position. However, there are two main limitations with this method to be applicable for measurements during surgery. Firstly, there are patients who suffer from eczema in the ear canal, congenital malformations, draining ears and chronic ear infections and this method cannot be applicable for them since it is not possible to enter the ear canal. Secondly, the position is too close to the position of the surgery, which is sterile. It would not be possible to reach the ear canal since the pinna, which is sterile, is folded above the ear canal. In the first part of this thesis, nasal sound pressure (NSP) method has instead been proposed to verify the functionality of BCI [8]. The main purpose of the test was to assure that the device work properly as there is always a risk for the implant to be damaged during surgery or during the preceding sterilization process. The secondary goal for this assessment procedure was to build a reliable reference to be used for further evaluation and analysis of the implant after the surgery in follow up stages. However, such method requires a lot of equipment, attention and knowledge to be used during surgery. This method is ideal to be used for research and/or follow-up of the patients.

1.1 Aim of study

The main purpose of this study is to design and develop a stand-alone device which enables a clinician to be assured about the functionality of BCI. The device is primarily assumed to be used during surgery to verify the proper functioning of the BCI and so that it can be used in surgery room without any additional equipment required.

2

Background

IN this chapter a brief background about bone conduction hearing is given. The aim is to familiarize the reader with available alternative treatment solutions for hearing impaired that can use bone conduction implant devices. Also a brief summery about the first phase of this thesis is given. More details and information about hearing and other types of hearing aids can be found in the first phase of this thesis project [8].

2.1 Bone Conduction Hearing

A hearing perception can beside the usual air conduction route also takes place through bone conduction (BC). Hearing through bone conduction as a phenomenon was first described in the 19th century [9]. It refers to the ability of hearing through vibrations in the skull or bones of the body that transmit the vibrations and end up with a hearing sensation. In other words, the effect of surrounding sound waves on the skull will result in mechanical stimuli of the skull and gives an auditory sensation. This phenomenon is particularly used in testing hearing thresholds to determine type of hearing loss by

2.2. BONE CONDUCTION STIMULATION

showing the difference between bone and air conduction thresholds [9]. While producing vocalization, the vocal cords, teeth and oral cavity will vibrate and this vibration is transmitted into the inner ear, creating BC hearing. The skull bone vibrates and based on the stimuli's direction, the stapes remain steady or start vibrating with a delay because of the inertia. These vibrations will then result in vibrating the cochlear fluid and cause hearing sensation [10]. The factors that contribute to a BC sensation could be summarized as radiation of sound in the ear-canal, inertia of ossicles and cochlea fluid, cochlear wall compression and transmission of pressure through cerebrospinal fluid [11]. Figure 2.1 shows both AC and BC hearing's contributing factors from both direct BC stimulation and BC stimulation through the skin. The dashed arrows represent one's own voice pathway of sound transmission while the solid arrows show two different hearing pathways; i.e. BC (both direct and through skin) and AC hearing [12].

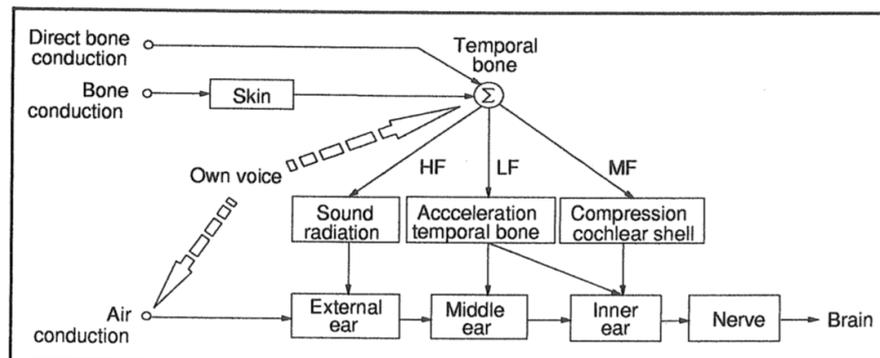


Figure 2.1: Contributing factors of AC and BC sound. The dashed arrows represent one's own voice pathway of sound transmission while the solid lines show two different hearing pathways; i.e. BC and AC hearing. As seen in the figure, in BC hearing pathway the sound will be transmitted more or less directly to the inner ear [12].

2.2 Bone conduction stimulation

There are some drawbacks about the conventional transducers for BC hearing aids and threshold testing which are related to their general design. A new version of bone con-

duction transducer, which has a small size, high efficiency and more improved linearity, is termed as the Balanced Electromagnetic Separation Transducer. For more details about the transducer (BEST), see Håkansson (2003) [13].

2.3 Deafness and Hearing Loss

Hearing losses can be classified as sensorineural, conductive or a combination of both called mixed hearing loss. Patients with sensorineural hearing loss will be treated in a great majority with air conduction hearing aids, which collects sounds from the environment by a microphone, then processing and amplifying the sounds [11]. The sound intensity is amplified to an appropriate level and then it will be fed to a miniature loudspeaker [14].



Figure 2.2: Air conduction hearing aid [15].

2.4 Bone Conduction Hearing Aids

Although a bone conduction hearing aid consists of the same microphone, amplifier and processor like in an air conduction hearing aid, a vibrating transducer is used as a loudspeaker [16]. Bone conduction hearing aids works by increasing the natural bone conduction transmission as a pathway for sounds to be able to travel into the inner ear, while bypassing the middle ear and external auditory canal [14].

2.4.1 Conventional Bone Conduction Hearing Aid

In the early twentieth century, the electric BC hearing aid was designed for the first time [17]. A BC transducer was placed onto the skin over the skull bone by a soft-band or headband and the microphone was usually positioned on the opposite side of the head in order to prevent acoustic feedback. However, the soft tissue between the skull bone and transducer acts like a low-pass filter, which attenuates the high frequencies and affects the hearing quality by performing poorly at high frequencies. Besides, the continuous pressure applied to the skull bone causes pain and annoyance and if the microphone is close to the transducer, feedback occurs.



Figure 2.3: Conventional BC hearing aid with a headband [11].

2.4.2 Percutaneous Bone-Anchored Hearing Aid (BAHA)

Since the conventional BC hearing aid faced some drawbacks, a more sophisticated version of BC hearing aid was needed for the patients with single sided deafness and conductive hearing loss. The development of a new BC hearing aid, BAHA, started in 1977 and three patients were operated initially that year [11]. Today, more than 100 000 patients have been treated with a BAHA (Cochlear, 2013).

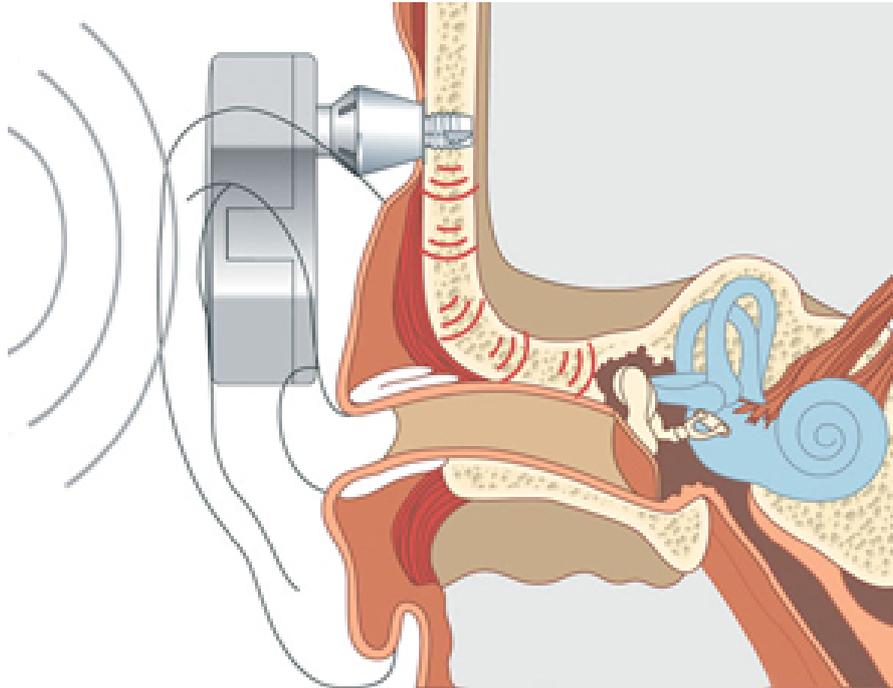


Figure 2.4: Bone Anchored Hearing Aid [18].

2.4.3 Bone Conduction Implant (BCI)

As a further development of the BAHA, a transcutaneous BCI system was developed at Chalmers University of Technology and Sahlgrenska University Hospital. This new system leaves the skin intact by placing the implant inside the skull bone closer to the cochlea. As it is shown in figure 1.1, the BCI system is divided into an external part, an implanted unit and an inductive link. The external part consists of a microphone, analog and digital signal processor and tuned driver, which transmit the signal and the sound waves energy into the inductive link. The implanted unit, called the Bridging Bone Conductor (BBC) unit, includes transducer, the receiving coil and tuned demodulator [11], [6]. The transducer of a BCI system is a vibrator of BEST type. An amplitude modulation is applied to transmit the signal to the transducer. After amplitude modulation of the sound data to a radio frequency carrier, the data is transmitted through the inductive link. A permanent magnet retention system is used in order to keep the

transmitter and the implanted receiver coil attached [14]. The excitation point of such a BCI system is closer to the cochlea than the excitation position for the BAHA system, which results in an increased sensitivity [3]. Studying related literature, measurements on both cadaver [19] and dry skull [20] show that the vibration in cochlea will be increased as the excitation point gets closer to the cochlea. Reinfeldt et al. [3] showed that the increase in vibration of the cochlea means increased hearing sensation [3].

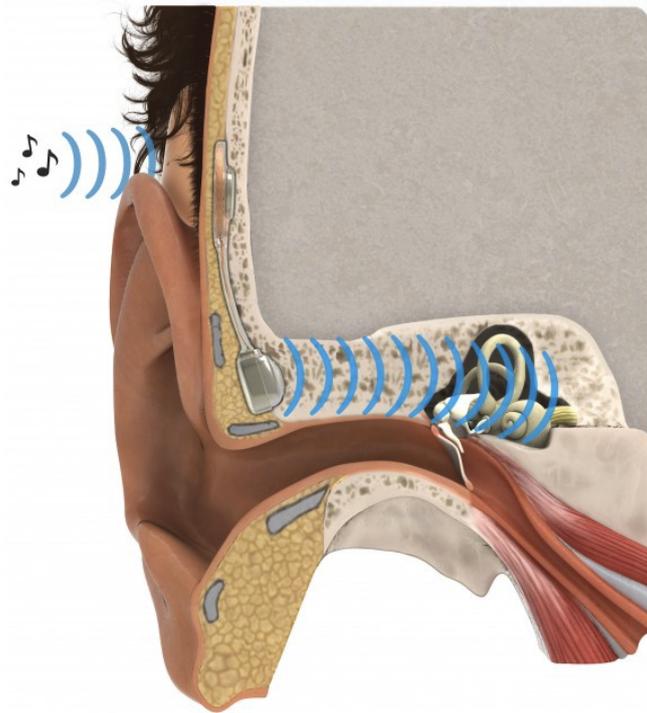


Figure 2.5: Function of Bone Conduction Implant (BCI). The sound is received by the sound processor attached outside the skin and transmitted to the implant where the transducer provides a vibration corresponding to the received sound. The vibration is sensed by the cochlea, giving a hearing sensation [21].

2.5 Summery of the first phase

This first phase of this thesis project primarily aimed to develop a non-invasive intra-operative method to verify the functionality of a new Bone Conduction Implant (BCI)

using Nasal Sound Pressure (NSP) before the surgical incision is closed. The reason behind this verification process was due to the risk of damages to the implant, during surgery or during the preceding sterilization process. In addition, this method was intended to be used in further evaluation and analysis of the implant after the surgery in follow-up stages. Previously Ear-Canal Sound Pressure (ECSP) had been suggested and investigated as a method to verify the function of the BCI during and after surgery. However, the ear-canal is close to the surgical site and difficult to reach during the surgery, and some patients do not have ear-canal. To evaluate the efficacy of the NSP method, the technique was optimized by performing preparation measurements on authors using bone conduction stimulation through the skin. Then, the method was tested on a cadaver by both bone conduction stimulation through the skin and direct bone conduction stimulation from the implanted BCI transducer. In the next stage, 20 normal-hearing subjects participated in the study to evaluate and compare the efficiency of NSP and ECSP before testing the NSP method during surgery on the first BCI patient. Figure 2.6 shows the results from NSP measurements on 20 normal-hearing subjects.

Different factors and constraints which can affect the results were considered and this study showed that the NSP provides higher magnitude than the ECSP. Stimulation at BCI position provided a higher NSP signal than stimulation at the BAHA position, which is consistent with results from previous studies investigating hearing thresholds, ECSP and vibrations of the cochlear promontory.

The results clearly implied that the NSP method is suitable for the test and verification of the implanted part of the BCI. This has been confirmed in the first surgery. The NSP method is also used in the follow-up of patients to verify the functionality of the implanted unit of the BCI. One other important feature which has been discovered during surgery was that the sound from the implant propagated to surrounding environment during NSP measurement in the operating theater [8].

2.5. SUMMARY OF THE FIRST PHASE

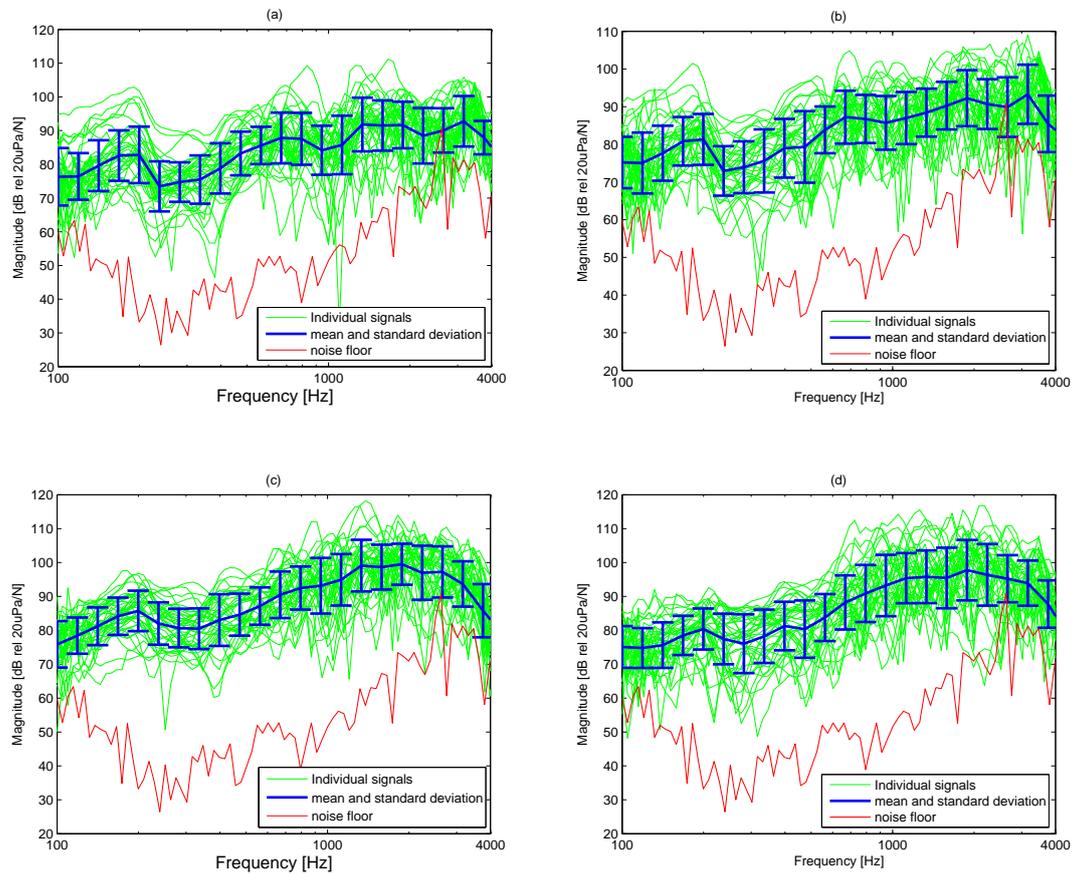


Figure 2.6: a: NSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position A** (BAHA position); Average of 40 NSP signals (left and right together); noise floor (Red). b: NSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position A**; Average of 40 NSP signals (left and right together); noise floor (Red). c: NSP measurement from 20 normal hearing subjects, **ipsilaterally**, for stimulation at **position B**; Average of 40 NSP signals (left and right together); noise floor (Red). d: NSP measurement from 20 normal hearing subjects, **Contralaterally**, for stimulation at **position B** (Green); Average of 40 NSP signals (left and right together); noise floor (Red) [8].

3

Possible solutions

INITIALLY, a number of different solutions have been considered as possible methods to verify the functionality of the BCI. These approaches were investigated in design phase and are explained in the following sections. It is desirably to design and implement a device that works with 1.4 VDC battery in order to use the same housing and audio processor that is used for the BCI.

3.1 Verification using electrical stimulation

3.1.1 Signal generation

The first step in verification of the performance of BCI is to generate a known signal which is transmitted to the implant. By obtaining a response signal, the verification can be done. In the previous phase of this thesis, both in normal hearing subjects and patients measurement, sine waves with frequencies from 100 to 10000 Hz was used to stimulate the BBC. Therefore, in this phase of study the first attempt was to generate a pure sine wave as the stimulus from a stand-alone test device. Different possible solutions have been investigated for producing pure tones including:

- Oscillators
- Sine wave generator ICs
- Field Programmable Gate Array (FPGA)
- DSP

Oscillators

Suitable selection of feedback-loop parameters in an active filter circuit can cause intentional oscillation at a desired frequency [22]. Simple filters such as RC filters can be used to shape the waves based on the needs. For example, a Wien-bridge oscillator can be used to generate a sine wave. Figure 3.1 shows the schematic of the Wien-bridge. A sinusoidal wave can be generated by choosing the appropriate values for R_1 and R_2 to satisfy an unstable condition for the amplifier and desired frequency can be achieved by adjusting the two RC filters. The frequency can be adjusted to approximately 1 kHz, having $R_1=R_2 = R = 10k\Omega$ (Eq. 3.1.1) and $C_1 = C_2 = C = 15nF$. To have access some other frequencies, it is possible to place a potentiometer to change the voltages over the RC filters. It is usually required to use more filters to shape a pure sine wave.

$$\omega = \omega_f = 1/RC$$

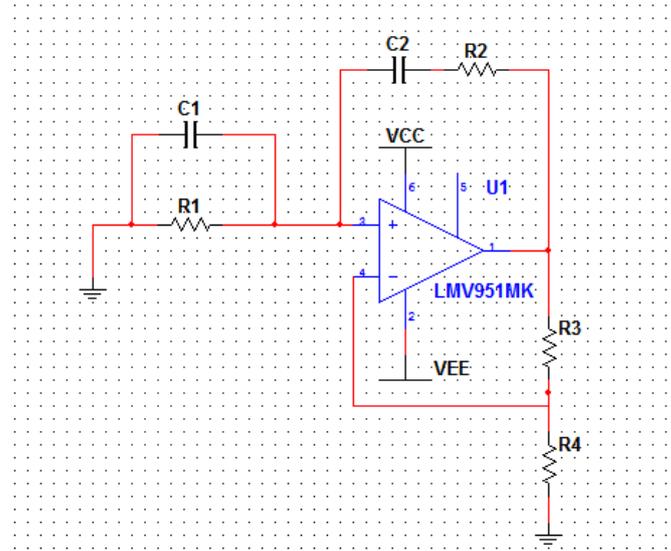


Figure 3.1: Wien-bridge oscillator circuit.

Sine wave generator ICs

There are variety of ready modules that can provide different types of periodical waves including sine waves. These ICs can be employed in BCI verification. Some of the available ICs are programmable and they provide features that can be used to measure frequency response function over a frequency range. This is a significant advantage because it would not be necessary to include another units for the frequency analysis in the design. However, most of the available ICs in this catagory usually work with power supply more than 1.4 V which is the implemented battery in the BCI audio processor.

One of the available ICs is AD9833 from ANALOG DEVICES which can be used as the signal generator and frequency analysis unit. It is a low power, programmable waveform generator capable of producing sine, triangular, and square wave outputs. Some of its important features are:

- Digitally programmable frequency and phase
- 2.3 V to 5.5 V power supply

- 0 MHz to 12.5 MHz output frequency range
- Sinusoidal, triangular, and square wave outputs
- Power-down option
- 12.65 mW power consumption at 3 V
- 3-wire SPI interface
- 28-bit resolution: 0.1 Hz at 25 MHz reference clock

Field Programmable Gate Array (FPGA)

It is also possible to create different types of waveforms by FPGA. This can be done using different mathematical algorithms or simply by using a look-up table. A number of sine waves with different frequencies can be picked up from the look-up table automatically or by pressing a push-button. The FPGA can also be used for frequency analysis, however, more complex design and programming is required to do the FFT.

DSP

In the BCI, a R3910 pre-configured DSP has been used for the digital signal processing part as it is described in section 4.1[14]. As it can be seen in the block diagram of the R3910 (see figure 4.1), there is a possibility to generate tones with different frequency. The main purpose of this tone generator is to be used as the indicator for the users to switch between the programs in their audio processors. If this signal can be created and transmitted through the inductive-link to the implant, then it would be the most optimum way to generate sine waves [23].

3.1.2 Signal transmission

In order to transmit the generated signal to the implant, the BCI audio processor is used. The signal is transmitted via an inductive link by an AM modulation method. The transmitted signal is then received by a receiver coil and converted into mechanical vibration by a bone conductor transducer after demodulation 1.1.

3.1.3 Signal verification

Previously, in the first phase of this thesis, Nasal Sound Pressure method was proposed for verification of the BCI [24]. The sound signal is picked up from the nostril via a probe-microphone and amplified before calculating the NSP. Finally, the amplitude of the frequency response function is compared to the reference level which had been investigated in the normal-hearing study and the patient measurements in the first phase. Furthermore, in the first surgery, it has been discovered that the sound which is propagated in surrounding environment of implant during the NSP measurement can be sign and a very effective verification tool.

The functional block diagram of a verification method using NSP can be seen in figure 3.2.

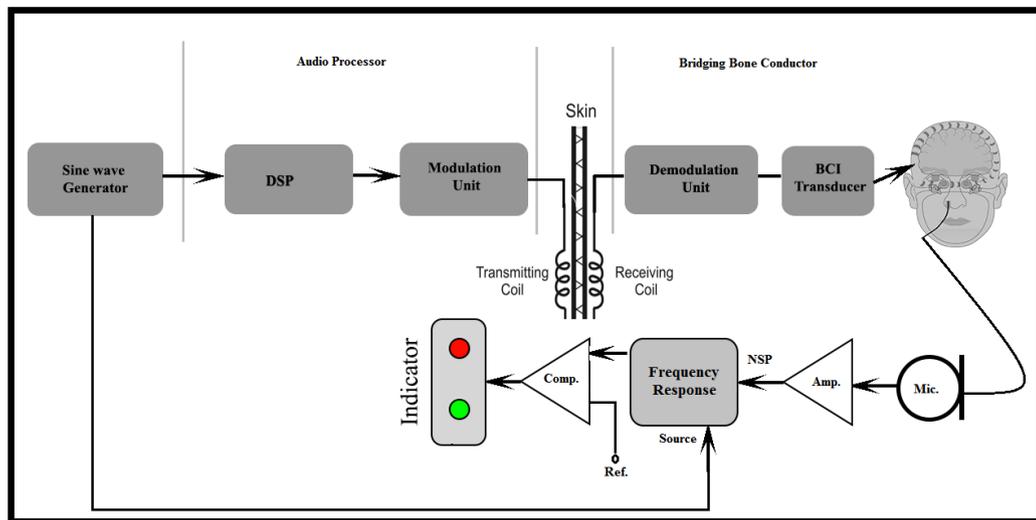


Figure 3.2: The functional block diagram of BCI verification using NSP.

4

Digital Signal Processing

The revolutionary role of digital technology for the improvement of new devices is highly clear. Today, Digital Signal Processing units have a significant role in development of medical devices especially in hearing aids. The hearing aid DSPs can be customized at individual level based on types of hearing losses. This capability has given excellent results since its introduction. Adaptive noise suppression and feedback cancellation methods based on surrounding environments or tinnitus treatment are among the advantages of using this technology. In this chapter the DSP that has been used for BCI is introduced.

4.1 DSP model and its features

The implemented DSP in this project is RHYTHM R3910 from ON Semiconductor. R3910 is a pre-configured DSP for hearing aids with up to 8 WDRC channels. This model provides many features including:

- 128-band Adaptive Noise Reduction
- Adaptive Feedback Cancellation (AFC)

- Tinnitus Masking Noise Generator
- Evoke Acoustic Indicators
- Feedback Path Measurement Tool
- Narrow-Band Noise Stimulus
- Automatic Adaptive Directional Microphones (ADM)
- Auto Telecoil with Programmable Delay
- AGC-O with Variable Threshold, Time Constants, and Optional Adaptive Release
- 16-band Graphic Equalizer
- SDA or I2C Programming
- 8 Biquadratic Filters
- 4 Analog Inputs
- 20-bit Audio Processing

4.2 Signal path

Front microphones is the first main audio input signal path to the DSP. The second path belongs to the rear microphone, telecoil or direct audio input which can be chosen by a programmable input selector (MUX). In FrontWave feature, ADM, two microphone input data is used (front and rear) so that the instrument can mimic a directional hearing sensation to the patient. Input signal are buffered, sampled and digitized using dual A/D converters thereby converted into 16 kHz or 32 kHz, 20-bit audio signal. Afterwards, the IIR filter blocks are applied to the digitised signal. To match the gain of front and rear microphone signals a biquad filter is used. Later, the signals pass through four cascade

biquad filters (pre1 to pre4) for frequency response shaping before it passes through tuning and adaptive processing blocks. The tuning and adaptive processing consists of the following:

- Frequency band analysis
- 1, 2, 4, 6 or 8 channel WDRC)
- 16 frequency shaping bands (spaced linearly at 500 Hz intervals, except for first and last bands)
- 128 frequency band adaptive noise reduction
- Frequency band synthesis

After processing, there are two more biquad filters, post1 and post2, then the signal goes through AGC-O block which is responsible for wide-band gain and volume control. Two other biquad filters (post3, post4) and a peak clipper are applied after AGC-O. The last stage is the digital to analogue converter (H-bridge). For tinnitus treatment, a white noise can be shaped and attenuated before it is added to the signal path. It can be programmed either before or after volume control.

The functional block diagram of the DSP is shown in figure 4.1.

4.3. FUNCTIONAL BLOCKS

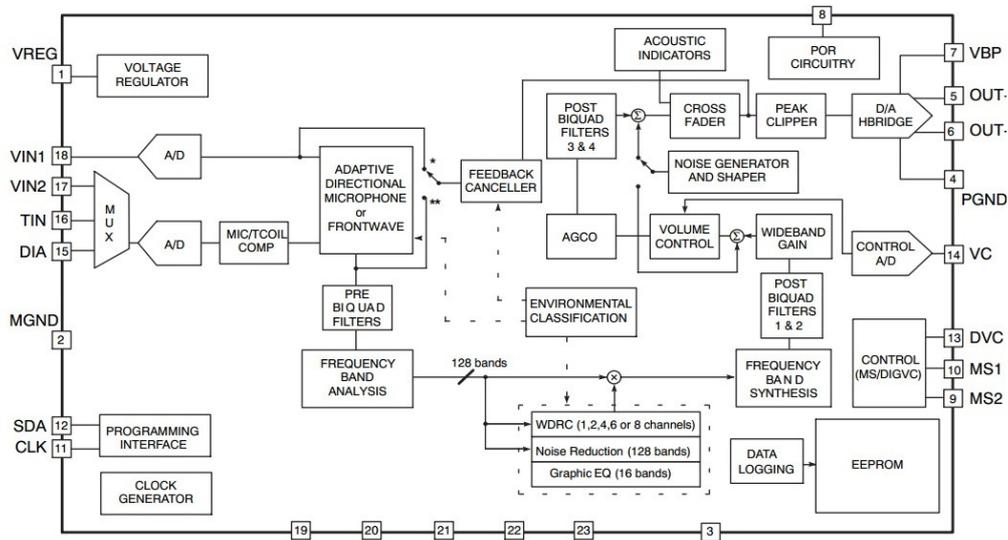


Figure 4.1: Hybrid Block Diagram.

4.3 Functional blocks

4.3.1 Feedback path measurement

The feedback path measurement tool is one option in the pre-configured DSP RHYTHM R3910 that employs built-in features to measure maximum stable gain (MSG). The MSG provides important and useful information which can be used during design and fitting phases.

4.3.2 EVOKE advanced acoustic indicators

This feature provide acoustic tones which are used as indicators with more complex characteristics than its previous products. This capability can provide a more meaningful indicator sounds by having smooth on and off transition effect or damped, multi-frequency tones that can be used to generate a short music piece as an indication for the end users. These indicator sounds can be allocated to each of ten events including selection of memories (A,B,C,D,E or F), warning for battery status and digital volume control changes. Each sound can be generated by a number of pure or damped tones.

4.3. FUNCTIONAL BLOCKS

The frequency, amplitude, start, end and decay time can be adjusted in Evoke Editor interface based on desire and interest of end-users. The figure 4.2 illustrate the interface of Evoke editor.

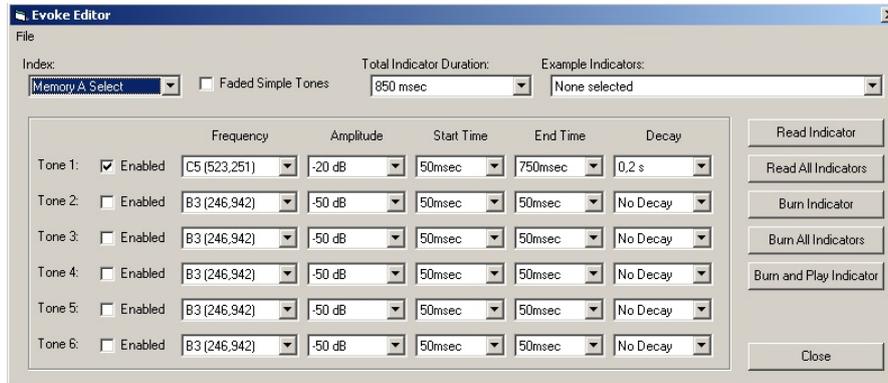


Figure 4.2: Evoke editor.

4.3.3 Tinnitus Treatment

A broadband noise generator has been equipped in Rhythm R3910 for patient suffering from tinnitus. The gain can be adjusted to a level to either mask or draw attenuation away from patients' tinnitus. The frequency band-width of the noise can be shaped using the low-pass and high-pass filters with adjustable cut-off frequencies.

The ARK software provides a tool to simply configure a noise for treatment of tinnitus. The noise can be injected before or after the volume control (see figure 4.1).

5

Method

5.1 Measurement method using electrical signal

One method to verify and confirm the proper functioning of BCI is usage of electrical stimulation of the BBC. By transmitting a signal with proper frequency and amplitude to the implant, sound waves are propagated in skull and emitted to the surroundings which then can be perceived as a subjective measure that reflects the functionality of the device. The block diagram of the test device is shown in figure 5.1.

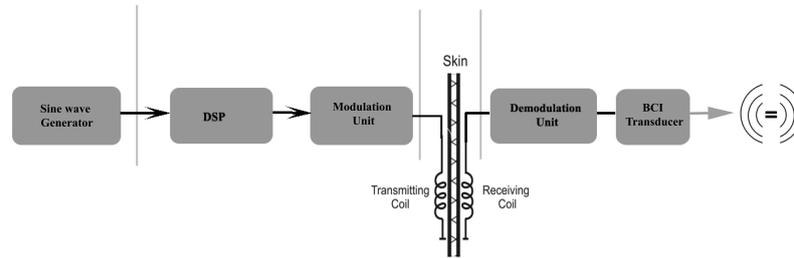


Figure 5.1: BCI tester using indicator signals.

5.2 DSP programmer

DSP programmer GENNUM[®] version 1 (see figure 5.2) is used to write, read and burn the desired parameters for different configuration on the DSP R3910. It is connected to the computer via a USB connection and to the DSP with a SDA communication cable. A program called Interactive Datasheet is used as a graphical interface to the DSP. The programming setup is shown in figure 5.3.



Figure 5.2: (A) DSP programmer GENNUM-V1, and (B) SDA and USB cables.

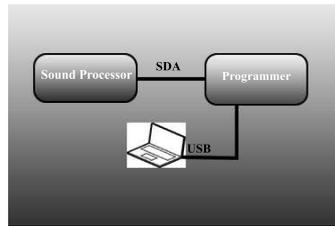


Figure 5.3: programming set up.

5.3 EVOKE indicators

EVOKE advanced acoustic indicators is a feature which can be used to electrically stimulate the implant. Six tones from low to high frequencies can be assigned to each event (A, B, C, D, E, F). By pressing the push-button on the audio processor each time six selected tone compositions are generated and transmitted to the implant. The allocated frequency to each tone is equivalent to musical tone and they cover frequencies from C4 (261 Hz) to C7 (2093 Hz). In addition to mentioned musical frequencies, pure tones with frequencies from 3 kHz to 8 kHz can also be used.

5.3.1 Programming indicators

After connecting the audio processor to the programmer and computer, the evoke editor can be launched from Tools > Evoke Editor menu. The editor would allow us to change different parameters including frequency, amplitude, start and end time. In addition, the total time interval for indicator and decay time for each tone can be chosen. Each of acoustic indicators sound can be programmed and edited from the drop-down list in section called, Index. See figure 4.2.

Once the desired parameters have been chosen, then it can be played to see if it satisfies the needs. Afterwards, the desired configuration of the indicators must be burned on the DSP. Different options on the editor for reading, playing and burning are listed below:

Burn and Play Indicators: Burns the selected acoustic indicator into the device

and plays it.

Burn Indicator: Burns the indicator but does not play it.

Burn All Indicators: Burns all the indicators into the device.

It is possible to save configured parameters for the indicators as a xml file into the computer so that it can be loaded to the DSP later on when it is required. The save and load option can be found from file menu in the Evoke editor.

5.4 Noise stimulation using tinnitus treatment

The possibility of generating the broadband noise can be employed to stimulate the BBC. This feature is provided for treating the patients suffering from tinnitus. This stimulation can be heard in surrounding environment. The noise can be shaped and saved in memory A. In this case, once the device is turned on the noise will stimulate the implant so it can be used as a sign for verification.

5.4.1 Programming noise

After proper connection of the audio processor to the programmer and computer, the tinnitus is one of the items in the Intractive Data Sheet (IDS) (see figure 5.4). The position of noise insertion, either before or after the volume control can be chosen from noise insertion drop-down list. The noise level can be adjusted from -80 dB to -6 dB. The type and order of the noise can also be adjusted to shape the frequency band-width based on the needs of the patients.

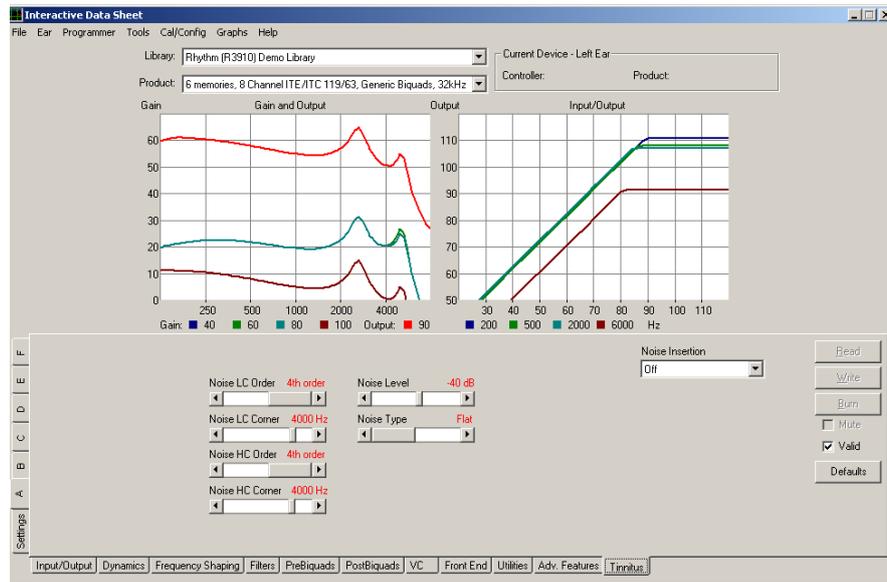


Figure 5.4: Noise shaping for tinnitus treatment.

5.5 Method evaluation

To investigate the efficacy of the device, two listening test were prepared and performed. In the first test, eight signals were assessed by subjects. In the second test, five signals were prepared for evaluation of the implemented device.

5.5.1 Listening test 1

A protocol for a first listening test using an evaluation table was prepared. The patient was a male BCI patient and he was on his six-month follow-up. The tests was performed in two phases, started by signal 1 to 4 then followed by signal 5 to 8. Signal number 5 was added after receiving feedback from investigators such that some higher frequencies were perceived better and easier. The patient with the implanted BCI was asked to sit on the chair in a sound insulated test room. In the first test, a flat noise was transmitted to the implant. The noise was generated in the DSP by using the tinnitus treatment feature. This noise was saved in memory A so once the device is turned on, the stimulation started spontaneously. Signal 2 and 3 utilizes tone indicators for the sound stimulus. In

5.5. METHOD EVALUATION

Table 5.1: Signals used in listening test 1.

Signal No.	Stimuli	Digital Volume	Frequency (Hz)					
			Time interval for each freq.= 1 Sec.					
Signal 2	Sine wave	-1 dB	880	987	1046	1174	1318	1396
Signal 3	Sine wave	-1 dB	1567	1760	1975	2093	2500	3000
Signal 4	4 Harmonics*	-1 dB	261	523	1046	2093		
Signal 5	Sine wave	-1 dB	1046	1046	2500	2500	3000	3000
Signal 6	Sine wave	-20 dB	880	987	1046	1174	1318	1396
Signal 7	Sine wave	-20 dB	1567	1760	1975	2093	2500	3000
Signal 8	4 Harmonics	-20 dB	261	523	1046	2093		

* In test number 4 and 8 all four tones are played simultaneously.

Signal 2, the sound consists of six tones with frequencies between 880 and 1396 Hz (see table 5.1). The sound signal 2 was saved and burned in memory C. The same routine was used for creating signal 3 in memory D. The different frequencies of each signal sequence is presented in table 5.1. The volume level of the generated sound was adjusted to the loudest possible range using digital volume control at -1 dB. Signal four consists of four harmonic tones which are played simultaneously for six seconds. This was saved in memory F. Signal 5 includes tones with frequencies at 1046, 2500 and 3000 Hz. Each tone is played two seconds with the loudest possible level as expressed above. The signals 6, 7 and 8 are the same as signals 2, 3 and 4 but with a lower volume set at -20 dB. This was planned in case that subject feels uncomfortable with the loudness of the generated sounds and more importantly to investigate in what extent the signals could be heard. However, the sound comfort would not be an issue during the surgery while the patient is unconscious.

5.5. METHOD EVALUATION

Table 5.2: Signals used in listening test 2.

No. test	Stimuli	Digital Volume	Frequency (Hz)					
Time interval for each freq.= 1 Sec.								
Signal 2	Sine wave	-1 dB	880	987	1046	1174	1318	1396
Signal 4	4 Harmonics*	-1 dB	261	523	1046	2093		
Signal 5	Sine wave	-1 dB	1046	1046	2500	2500	3000	3000
Test 9	Sine wave	-1 dB	880	1174	1396	1318	1174	1396

* In test number 4 all four tones are played simultaneously.

5.5.2 Listening test 2

Second listening test was first performed on the same male patient as test 1 and a test protocol with an evaluation table was prepared. Five participants have attended for this listening test. Based on first listening test some of the signals have been excluded and some modification also has been done. The first signal was set to be a broadband noise in the same way as in the first test. Signal 2, 4 and 5 have been chosen from the previous test and only test 9 was a new signal. The signal 9 is the first 6 musical notes of the song, "God Father". Table 5.2 shows the signals and corresponding frequencies for listening test 2.

6

Results & Discussion

After listening tests the evaluation tables were collected based on a subjective scale of loudness perceived by the four listeners. The loudness scale ranged from "0" corresponding to "not heard" to "5" corresponding to "clearly heard".

Signals 3 and 4 in the first test and signals 2, 4, 9 in the second test provide a better hearing level for the listeners. The broadband noise and signals 6, 7 and 8 with lower volume control level provide the lowest hearing, however, the noise was heard by all listeners. The first test indicates that the signal with higher frequencies and volume control at -1 dB can be heard best. The second test, not surprisingly, implies the same frequencies can be heard better if a higher volume control setting is used.

In the ninth signal the first six musical notes from a famous song has earned the second best result. Therefore, these types of signal can be properly used because listeners or testers have some expectations about what they are going to hear.

It is possible to have six signals in the device so that it can cover variety of signals and broader range of frequencies. It can be important to cover broader range of frequencies in case that the listeners in surgery room have some weakness in hearing. However, there are usually more than one person in surgery room and this should rarely happen.

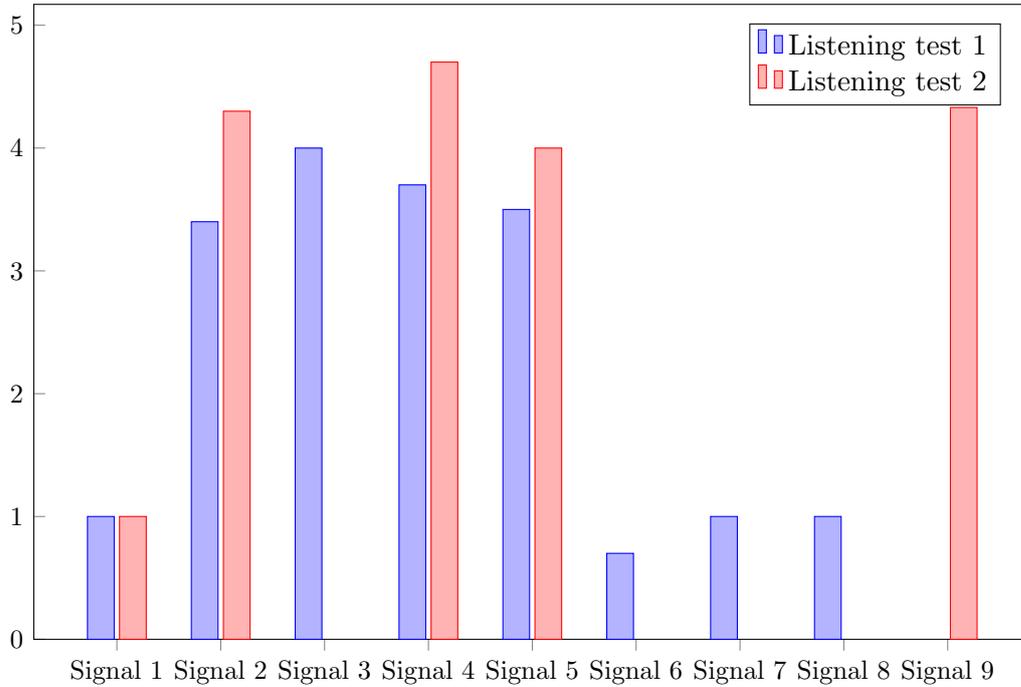


Figure 6.1: Chart shows the listening test, performed on two patients with four participants including two normal hearing and two non-normal hearing persons. They voted for loudness of the signals based on their hearing sensation from zero to five. Signal 1: Flat noise stimulation with volume control adjusted -6 dB; Signal 2: Pure tones from 880 Hz (A5) to 1396 Hz (F6) with volume control adjusted -1 dB; Signal 3: Pure tones from 880 (A5) to 1396 (F6) which form the first six notes of God Father with volume control adjusted -1 dB; Signal 4: Playing the tone with base frequency 261 (C4) together with its three harmonics for six seconds with volume control adjusted -1 dB. Signal 5: Three pure tones with frequencies (1864 Hz, 2500 Hz and 3000 Hz) each for two seconds long with volume control adjusted -1 dB; Signal 6: Pure tones from 880 Hz (A5) to 1396 Hz (F6) with -20 dB volume; Signal 7: Pure tones with frequencies (1567, 1760, 1975, 2500, 3000 Hz) adjusted at -20 dB volume control; Signal 8: Playing the tone with base frequency 261 (C4) together with its three harmonics for six seconds with volume control -20 dB; Signal 9: Six first notes of the musical peace.

7

Conclusions

The aim of this Master thesis was to develop a stand-alone test device, which can be used during surgery in order to assure functionality of a new Bone Conduction Implant (BCI). The results obtained from this thesis work clearly show that the implemented device can be used during or after surgery. Result shows that the higher frequency and harmonic signals were the most appropriate signals to be used in the BCI test device and it was heard by listeners almost 20 dB higher than the threshold of human hearing.

It is suitable to include signals which cover frequencies between 800 Hz to 4 kHz in order to assure that the listeners in surgery rooms can hear some of the tones even with abnormal hearing condition and thus subjectively confirm a proper function of the implanted BCI device.

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