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Expected Lifetime and Short-term Mechanical Vulnerability of the Bone Conduction Implant

Master's thesis in Biomedical Engineering

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Abstract

The bone conduction implant (BCI) is an active transcutaneous bone conduction device for rehabilitation of patients suffering from conductive or mixed hearing loss. Today, the device is used by 9 patients in an ongoing clinical trial, and it has been shown to provide sufficient rehabilitation for indicated patients. The objective of this project was to estimate the lifetime of the BCI through an accelerated test under continuous high input sound stimuli, and to investigate vulnerability to mechanical stress that can occur during surgery and normal conditions.

Two types of investigations were used: (1) A long-term sound exposure investigation was performed on one full BCI system in order to estimate the lifetime of the implant; (2) The robustness of one titanium cased transducer was thoroughly investigated by performing a series of mechanical investigations comprising: mechanical shock, random vibration, drop, and impact tests. The performance after each of these tests was evaluated by measuring the frequency response and the total harmonic distortion of the device on a skull simulator.

No change was detected in the performance after 5 weeks of the continuously ongoing sound exposure of the full BCI system. In the mechanical shock and vibration tests of the titanium cased transducer, the change in the transducer's frequency response was minor and assumed to be clinically insignificant.

The accelerated sound exposure indicates that the lifetime is at least 7.5 months based on the follow-up time until the end of this Master thesis project (assumed scaling factor of 6 times was used). This test will continue until a major change in performance occurs to find out the actual life time of this particular implant system.

All mechanical tests imply that the transducer is safe with respect to mechanical stress and no potential failure mode was detected. However, a larger study on greater number of transducers and full BCI systems are needed in order to get more statistically reliable results.

Acknowledgement

I would like to express my sincere gratitude to my supervisor Karl-Johan Fredén Jansson for all his invaluable guidance, support and discussions during the course of this thesis. I wish to thank Bo Håkansson for much appreciated advices, explanations and discussions about the project. Special thanks go to both of them for their participation and assistance with performing tests and measurements. Also, my sincere thanks go to Sabine Reinfeldt, my examiner, for her feedback and support with writing.
Finally, I would like to thank Oticon Medical for the use of their laboratory and equipment.

Contents

Abbreviations

AC	Air Conduction
AP	Audio Processor
ASD	Acceleration Spectral Density
BAHA	Bone Anchoring Hearing Aid
BBC	Bridging Bone Conductor
BC	Bone Conduction
BCI	Bone Conduction Implant
BEST	Balanced Electromagnetic Separation Transducer
dB	Decibel
FRF	Frequency Response Function
L_{eq}	Equivalent Continuous Sound Level
MPO	Maximum Power Output
OFL	Output Force Level
SPL	Sound Pressure Level
THD	Total Harmonic Distortion

1 Introduction

Sound can be conducted to the inner ear by two main mechanisms, air conduction (AC) and bone conduction (BC). AC is commonly referred to as the normal hearing mechanism where airborne sound is conducted from the outer ear, through the bones in the middle ear and to the cochlea in the inner ear. In BC, sound is conducted through the skull bone with vibrations to the cochlea. The concept of BC is used in so called bone conduction devices that are intended for hearing rehabilitation of individuals who suffer from conductive or mixed hearing loss. One such device is the bone conduction implant (BCI) which is a semi-implantable active transcutaneous bone conduction device (Reinfeldt et al., 2015a). The BCI consists of an implant located in the patient's temporal bone and an externally worn audio processor (AP) that is attached to the head with retention magnets. Audio signals are transmitted wirelessly from the AP to the implant using an induction link. The implanted transducer converts the audio signal to vibrations that are conducted through the skull and stimulate the cochlea. In the cochlea these vibrations are finally converted to nerve signals in the basilar membrane and conveyed via the auditory nerve to the brain which enables the patient to hear.

Today, nine patients are using the device in an ongoing clinical trial, and the first patient has used the BCI for more than 2.5 years. The accumulated follow up time among these patients is today more than ten years. So far the results are promising and follow-up studies have shown that the BCI provides significant rehabilitation for its indicated patients (Reinfeldt et al., 2015b). If the device fails after implantation, it does not only affect the hearing of the patient, but the patient also has to undergo another surgery to replace the device. Therefore, it is very important to be able to estimate the durability of the device and make sure that it functions properly.

The aim of this thesis is twofold. Firstly, to estimate the expected lifetime of the BCI through an accelerated test where the device is placed in a temperature of 37°C and exposed to continuous high input sound stimuli. Secondly, to investigate the BCI transducers vulnerability to mechanical stress that can occur under conditions of normal use or during implantation. This will be done by performing a series of mechanical tests that include mechanical shock, random vibration, impact and drop test. The performance of the device will be evaluated by measuring its frequency response and total harmonic distortion on a skull simulator.

2 Theory

2.1 Hearing

The ear is the part of our body that allows us to hear and is commonly divided into three parts: the outer, the middle and the inner ear. An illustration of the anatomy of the ear is shown in Figure 1. The outer ear consists of the pinna, which is the external part of the ear, the ear canal and the tympanic membrane. After the tympanic membrane comes the middle ear, which is an air filled cavity connected to the back of the nasal cavity via the eustachian tube. An ossicular chain made of three small bones called malleus, incus and stapes is located in the middle ear. The chain starts at the tympanic membrane and ends at the oval window that separates the middle ear from the inner ear. In the inner ear, the spiral shaped cochlea is located. It has three channels: the cochlear duct, scala vestibuli and scala tympani. The sensory hearing organ, called the organ of Corti, is located in the cochlea on the basilar membrane that separates the cochlear duct and the scala tympani. The vestibulum and semicircular canals, the organs for equilibrium and balance, are also located in the inner ear (Tortora & Derrickson, 2010).

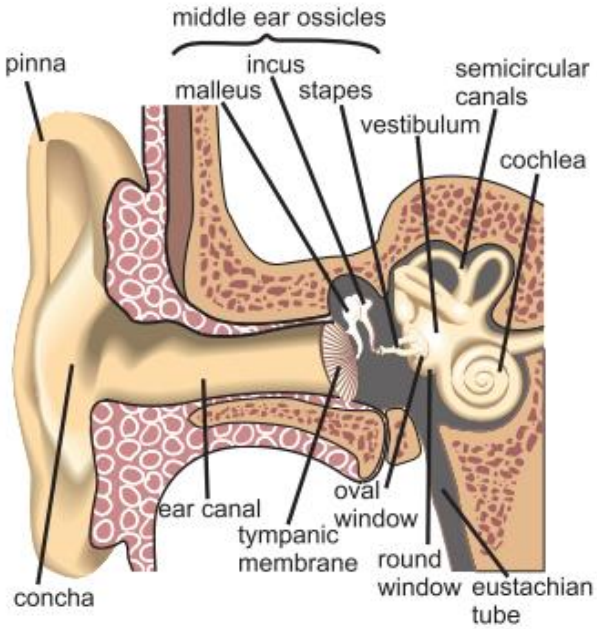

Figure 1: Anatomy of the human ear, the outer, middle and inner ear is shown (Taghavi, 2014).

Sound can be heard via air conduction (AC) and via bone conduction (BC) hearing. In AC hearing, the external ear receives sound waves that travel through the ear canal and hit the tympanic membrane, and causes it to vibrate. These vibrations are then transmitted through the ossicular chain and to the oval window. This will cause the oval window to move accordingly, which creates fluid pressure waves in the perilymph of the cochlea. These pressure variations are further transmitted to the round window through the scala vestibuli and scala tympani, causing the basilar membrane to move hair cells in the organ of Corti. This triggers the release of neuro transmitter molecules that are

conducted as nerve impulses to the brain via the vestibulocochlear nerve (Tortora & Derrickson, 2010).

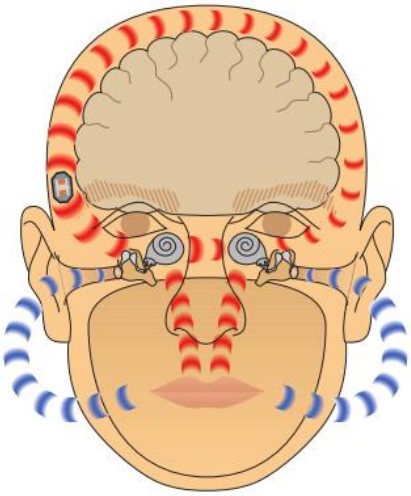

Figure 2: The different paths that are used in AC and BC hearing. The path used in AC hearing is denoted with blue and the one used in BC hearing with red (Taghavi, 2014).

In BC hearing, the sound energy travels through the bones in the skull bone with vibrations until it reaches the cochlea and vibrates the fluid inside it. This is enough to initiate nerve responses that are sent to the brain and interpreted as sound. The sound energy that is transmitted through the skull bone is a result of a person's own voice and surrounding sound. The surrounding sound can come from different directions, which means that vibrations in the skull can also travel in different directions (Taghavi, 2014). Figure 2 shows the main pathways for AC and BC hearing.

There are a few different factors that contribute to BC hearing, and their influence changes as a function of frequency. The five main factors are: (1) Inertia of the cochlear fluids, which is the biggest contributing factor and affects BC hearing below 4 kHz. (2) Middle ear ossicle inertia, which contributes to BC hearing in the frequency range of 1.5 – 3.1 kHz. (3) Sound radiated into the external ear canal is not significantly contributing, unless the ear canal is occluded, when it contributes at frequencies from 400 to 1200 Hz. (4) Compression of the cochlear walls mainly contributes to BC hearing at frequencies above 4 kHz. (5) Pressure transmission from the cerebrospinal fluid can trigger a sensation in the inner ear which is perceived as hearing (Reinfeldt, 2009).

2.2 Bone Conduction Implant

The bone conduction implant (BCI) is a semi implantable active transcutaneous bone conduction device that is intended for rehabilitation of patients suffering from conductive or mixed hearing loss. It consists of an externally worn audio processor (AP) and an implanted unit, called the bridging bone conductor (BBC). The AP comprises a retention magnet, two directional microphones, a modulator, a transmitting coil, a digital sound processor and a battery. The

sound is transmitted using an electromagnetic carrier wave from the transmitter coil to a receiver coil in the implanted BBC unit, which also comprises a retention magnet, a demodulator and a transducer (Reinfeldt et al., 2015b). In Figure 3, the different components of the BCI system are illustrated.

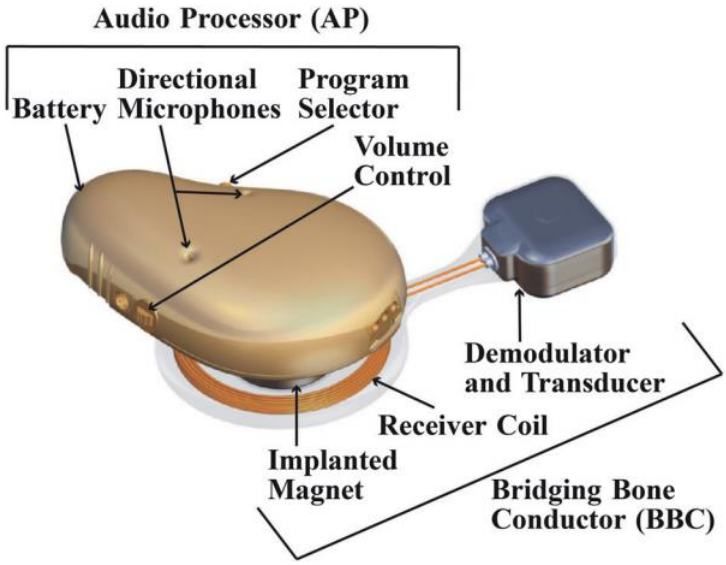

Figure 3: A 3D illustration of the BCI where the AP, the BBC and their components can be seen (Reinfeldt et al., 2015b).

The transducer in the BBC is based on the balanced electromagnetic separation transducer (BEST) principle with two damped resonance peaks, one low frequency peak around 800 Hz and a high one close to 5000 Hz. It has less total harmonic distortion (THD) at the same output force level as compared to conventional variable reluctance type transducers (Håkansson, 2003; Fredén Jansson et al., 2014). For biocompatibility it is placed inside a hermetic titanium casing. Almost the whole BBC is further sealed with silicone, except for one side of the transducer which faces the cranial bone.

During surgery, the transducer is implanted into the mastoid portion of the patient's temporal bone. It is located about 15 mm behind the ear canal opening, and is placed in a drilled recess that is about 4 to 5 mm deep. After implantation and healing of the wound, the AP is magnetically attached to the patient's head by the retention magnets. Audio signals that are picked up by microphones in the AP are converted to electrical signals for further transmission from the AP to the BBC via an inductive link. This is a wireless transmission that allows for sound to be sent through intact skin as electromagnetic signals. The signals are converted to vibrations by the transducer, and these vibrations by-pass the outer and the middle ear and are transmitted to the cochlea to give a hearing sensation. In Figure 4 it is shown how the BCI transmits sound via vibrations to the cochlea. By using the inductive link, the output power is reduced by approximately 10 – 15 dB in comparison with the direct drive stimulation of percutaneous bone anchoring hearing aids (BAHA). However, it was shown in a study by Reinfeldt et al. (2014) that this loss is regained by placing the transducer closer to the cochlea.

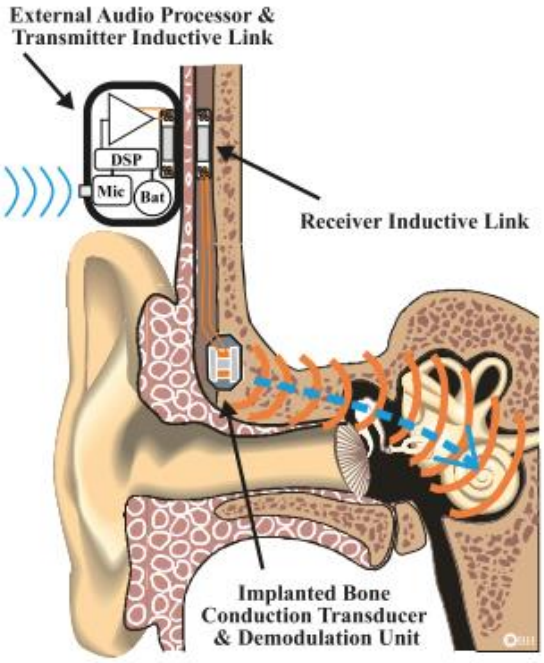

Figure 4: The BCI system with an external AP and the implanted BBC (Taghavi et al., 2012).

Today, the BCI is used by 9 patients in an ongoing clinical study and the first patient has had the device for over 2.5 years. The results are promising and the BCI has been shown to provide sufficient rehabilitation for its indicated patients. So far, the only objective measurement that has been made to verify the implant function over time is the frequency response of the nasal sound pressure when stimulating electrically. Also, audiometric testing and quality of life evaluation for the patients after receiving the implant have been made.

2.3 BCI Performance Measurements

2.3.1 Frequency Response Function

The frequency response function (FRF) of the BBC can be measured by stimulating it with a known sinusoidal input signal and measuring the output signal. It is obtained by calculating the ratio between the amplitude of the measured output signal and the amplitude of the input signal. Generically the FRF of the BCI is designed with two resonance peaks in order to widen the frequency range by using spring materials and masses in the transducer. Resonance frequencies can be calculated using equation (1). For the main resonance, C is the compliance of the main spring suspension used to maintain the needed air gap for these transducers, and m is the counteracting mass (Håkansson, 2003).

$$f_r = \frac{1}{2\pi\sqrt{mC}} \tag{1}$$

The spring suspension C also has a thin layer of damping material with high adhesion strength and a very good long term stability. However, its properties change with temperature, as it becomes harder when the temperature decreases and softer when it increases.

2.3.2 Output Force Level

The input signal to the AP is an airborne sound in the surroundings being picked up by the microphones and the output signal from the vibrating transducer is a force signal. It is therefore very informative to evaluate the device's performance by measuring the output force level (OFL) at constant input sound pressure level (SPL). When measuring the OFL for the BCI, it is typically stimulated at three different SPL: 60, 70 and 90 dB SPL. When the OFL is measured at 90 dB SPL the device is saturated and the resulting force level is the maximum power output (MPO) of the device. The MPO of the device is limited by the amplifiers, the transducer design and the voltage of the battery used in the AP. Most importantly, it is preferable to measure the MPO rather than the OFL at lower SPL when evaluating the performance. The latter can easily be very different because of different gain settings in the AP fitting, whereas the MPO determines the maximum possible output the system can deliver.

2.3.3 Total Harmonic Distortion

It is preferable that the device distorts the sound as little as possible, which is evaluated by measuring THD of the device. Harmonics occur at multiples of a fundamental frequency, and can be seen as peaks in the power spectrum of the signal. The THD is then calculated as the ratio of the power of all the harmonics excluding the fundamental (H_1) over the power of all the harmonics including the fundamental according to equation (2). Where H_n is the linear spectrum magnitude of the n^{th} harmonic and n is the number of harmonics (Fredén Jansson et al., 2014).

$$THD = \frac{\sqrt{H_2^2 + H_3^2 + \cdots + H_n^2}}{\sqrt{H_1^2 + H_2^2 + H_3^2 + \cdots + H_n^2}} \times 100\% \qquad (2)$$

For hearing aids, it is especially important that the THD is as low as possible in the hearing range, since higher THD means more distortion in the sound that the user hears. The THD is usually measured at 70 dB SPL.

2.4 Mechanical Testing

Active transcutaneous bone conduction devices, such as the BCI, are relatively new, and at the moment there are no standards for this type of devices. Therefore, applicable parts of voluntary standards for other implantable hearing devices, such as cochlear implants, are used instead. In order for an implantable medical device to be considered safe, it should withstand certain tests. These tests are designed to imitate circumstances that might occur during normal use or during implantation. The draft standard AAMI CI DRAFT 0.9 for cochlear implants specifies requirements on safety, performance and reliability of cochlear implant systems. This includes tests for random vibration, mechanical shock and mechanical impact (Association for the Advancement of Medical Instrumentation, 2015). Another test that is of interest, but not included in the standard, is a drop test. It is sometimes used to evaluate the robustness of

externally used BAHA audio processors when being dropped from different heights.

2.4.1 Mechanical Shock Test

The implantable part of an implant system should be able to withstand minor mechanical shocks that are likely to occur at any time before and during implantation of the device. According to AAMI CI DRAFT 0.9, the shock shape that should be used is a half sine or haversine wave with a duration of 1 ms and a peak acceleration of 5000 m/s^2, which translates to roughly 500 g. This shock should be applied to the implant once in each direction along three mutually perpendicular axes, which gives in total 6 different directions.

A mechanical shock test can be performed by dropping an object on a "hard" surface and measuring its acceleration when it hits the surface. When the object is dropped in a free fall, it approaches the surface with constant acceleration. Then it impacts and subsequently rebounds from the surface and its velocity and direction changes. Acceleration is described by the change of velocity over time and there is therefore a peak in the acceleration when the object hits the surface. By using this drop method it is very difficult to control the impact time as well as the acceleration peak as they are related to the material properties of both the implant under test and the hard surface. It was found that if a metallic pendulum rod is used to hit the metallic transducer casing, the impact acceleration can be several thousand g and the impact time will be much shorter than 1 ms, even if the drop is from a low height. Instead, a more reliable method to generate 500 g during 1 ms is to attach the implant rigidly to a solid fixture or frame which is freely (softly) suspended to a heavy support. An accelerometer is attached to the fixture in order to monitor the impact acceleration which can be injected by a pendulum arm with an appropriate material at the impact spot. It is a non-trivial task to find the requested acceleration curve, which is mathematically described as a half sine wave, according to equation (3), where Δt is the pulse width and $\frac{T}{2}$ is half the period.

$$a = a_p sin\left(\frac{\pi t}{\Delta t}\right) \qquad for\ 0 < t < \frac{T}{2} \tag{3}$$

Figure 5 shows a typical half sine acceleration curve. In the case of the mechanical shock test the pulse width required is 1 ms and the shock amplitude should be 500 g.

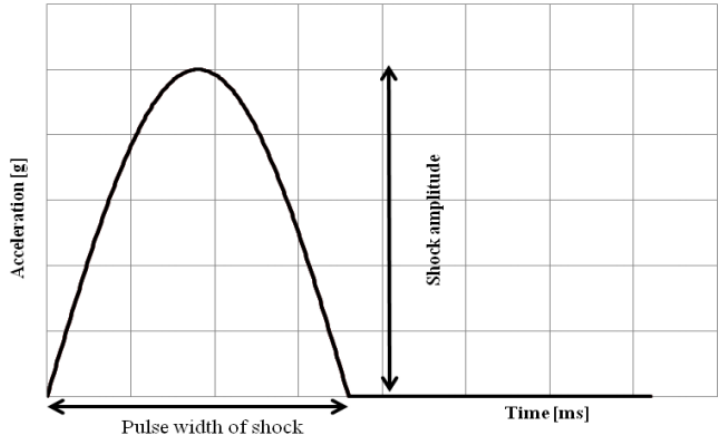

Figure 5: A typical half sine shock shape, like the one that should be used in the mechanical shock test. (Terefe, 2014)

2.4.2 Random Vibration Test

It is important for implanted medical devices to withstand vibrations, especially vibrations that occur during normal use by the patient after implantation. To test vulnerability towards vibrations, a random vibration test should be performed. According to AAMI CI DRAFT 0.9, the vibrations should be within the frequency range of 5 Hz to 500 Hz and the acceleration spectral density (ASD) should be a horizontal flat curve with the value of 0.7 $(m/s^2)^2/Hz$. The implant should undergo the test in three different directions along the three mutually perpendicular axes for 30 minutes in each direction.

When creating the desired vibration, one option is to use an electrodynamic Mini-Shaker type 4810 (Brüel & Kjær, Sound & Vibration measurement A/S, Denmark), which is driven by a signal source. Inside the electrodynamic shaker is a coil which is suspended in a fixed magnetic field. Vibrations are created when a current from the external signal source passes through the coil (Pauley, 2007; Lang & Snyder, 2001). An accelerometer is then used to measure the vibration response that is created and the ASD can then be calculated in order verify that the correct signal is being used.

2.4.3 Drop Test

AAMI CI Draft 0.9 does not specify that the implant should undergo a drop test from a certain height. The reason for this is that an implant already installed in the patient cannot be dropped for obvious reasons. If an implant is dropped before implantation it is normally capsuled in a sterile transportation casing and thus also mechanically protected. If it is dropped naked on the floor during the surgery it should be regarded as defective. Also, to care for micro shocks during surgery and handling in the sterile area at installation, the mechanical shock test described above is used. However, externally worn percutaneous BAHA with the transducer incorporated, might be frequently dropped and for that reason it is often of interest to see how they would withstand a fall from a known height. As this method was developed for a BAHA and available, it was decided to use the same method for the BCI. When BAHA is used, the height that it could be

dropped from could be quite high and levels up to 1-1.5 m are used when testing the device. In the case of the BCI, it was decided that 0.5 m was more appropriate. This could correspond to a drop onto the patient's bed or sterile tables over which the implant is handled.

A drop test can be performed with a similar method as was described for the mechanical shock test. When an object is dropped its velocity increases due to the gravitational force and the velocity at a certain time can be calculated by equation (4), where t is the time and g is the gravitational acceleration. The distance (d), travelled by the object, also increases as time passes and can be described by equation (5). By combining these two equations, the velocity of the object just before it hits the ground can be obtained by using equation (6).

$$v = gt \tag{4}$$

$$d = \frac{1}{2}gt^2 \tag{5}$$

$$v = \sqrt{2gd} \tag{6}$$

The mechanical energy of a pendulum is conserved and transforms between potential and kinetic energy. When a pendulum rod is raised to an angle θ_{max} the potential energy is maximized and the kinetic energy is zero, when the rod swings through its lowest position, the potential energy is zero and the kinetic energy is maximized, see Figure 6. The kinetic energy at the lowest position can therefore be obtained by equation (7), where m is the mass, v is the velocity and h is the height that the rod was released from. Furthermore, the velocity at the lowest position can be obtained by equation (8), which is the same as equation (6).

$$KE = \frac{1}{2}mv^2 = mgh \tag{7}$$

$$v = \sqrt{2gh} \tag{8}$$

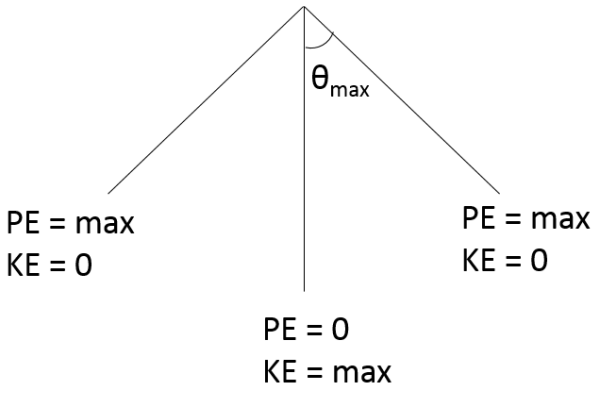

Figure 6: A diagram explaining the conservation of energy of a pendulum.

Under the assumption that any bouncing from a direct drop onto the floor can be neglected, placing the implant on the floor and hitting it with a pendulum rod released from height h, gives the same impact as dropping the implant directly on the floor from that height. The angle (θ) that the arm has to be raised to in order to simulate a drop from the desired height (h) can be calculated using equation (9), where L is the length of the pendulum rod. Figure 7 explains the angular position of the rod, the drop height and the length of the rod.

$$\theta = \cos^{-1}\left(1 - \frac{h}{L}\right) \tag{9}$$

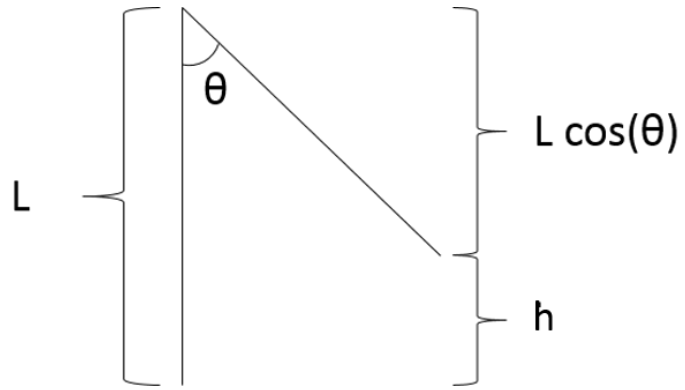

Figure 7: An explanation of how to relate the pendulum angular position to the drop height that is needed to achieve a certain mechanical shock pulse.

The impact surface of the pendulum rod, as well as the implant, will have a significant effect on the impact acceleration peak (in a perfect lossless impact the acceleration will be infinity). In literature, it is specified that this pendulum therefore should have a certain elastic modulus and damping properties that can be achieved by using a certain type of wood.

2.4.4 Mechanical Impact Test

The implant also has to undergo an impact test that exposes the device to an external impact when the implant is resting on a firm and solid base. This impact test is done in order to expose the device to shocks that could occur during normal use after implantation, for example during trauma and other external impacts. The implant acceleration is very low in these situations since the whole skull follows the implant. Instead this test is used to evaluate how well the implant can withstand compression impacts. According to AAMI CI Draft 0.9, the implant should withstand an impact of 2.5 J. A pendulum hammer or vertical hammer should be used to perform the test and the implant should rest on a rigid flat surface. The surface of the implant that faces the cranial bone during normal use should face this rigid surface, and the surface of the implant that faces the skin should be the surface that is impacted. A protective layer of 3 mm thick silicone should be placed on top of the implant to act as skin between the hammer and the top surface of the implant. The hammer should hit the implant perpendicularly at the centre of the implant.

In the case when a vertical hammer with a specified spherical tip is used to perform an impact test, a weight is raised to a height and then dropped vertically onto the object that is being tested. In order to make the weight fall directly on the object, it is usually guided down in a tube or by rails. The energy that the impact creates when striking the implant is equal to the potential energy that the mass has before it is released, see equation (10). The height that the mass has to be raised to in order to create an impact of a certain energy can therefore be calculated with equation (11).

$$U = \frac{1}{2}mv^2 = mgh \tag{10}$$

$$h = \frac{U}{mg} \tag{11}$$

2.5 Sound Measurements

Airborne sound can be characterized as pressure variations that can travel in longitudinal waves through different media, such as air or liquid. These sound waves have characteristics like frequency, amplitude, wavelength and period, and their propagation speed depends for example on the medium that it travels through and its temperature. The sound that surrounds us every day is a complex mixture of many sound waves and is usually characterized by its spectrum (Hansen, 2001). In theory, there is no difference between sound and noise, as noise is usually defined as unwanted sound. It is therefore a very subjective evaluation, since what one person would consider as noise, another would consider as sound.

The human ear has a very large dynamic range, it can detect a minimum sound pressure of 20 μPa and the pain threshold is considered to be about 20 to 60 Pa. To facilitate working with such a wide range, a logarithmic scale in decibels (dB), which represents the ratio of the actual measured sound pressure and a reference pressure, was introduced. In equation (12), it is shown how to obtain the SPL in dB, where p_{rms} is the actual sound pressure and p_{ref} is the reference sound pressure which is equal to 20 μPa. The obtained sound pressure level L_p in decibels can therefore be either above or below the 20 μPa reference value, since this method is based on the ratio of p_{ref} and p_{rms} (Hansen, 2001).

$$L_p = 10\log_{10}\frac{p_{rms}^2}{p_{ref}^2} = 20\log_{10}p_{rms} - 20\log_{10}p_{ref} \quad \text{(dB SPL)} \tag{12}$$

Furthermore, the sensitivity of the human ear is not equal for all frequencies, which is usually compensated for by using frequency weighting. By using frequency weighting, each frequency will be adjusted and contributes to a change in the overall sound level (Hansen, 2001). There exist several different types of frequency weightings. The most common ones are the A and the C weighting, see Figure 8. In order to know what type of weighting has been used

in SPL measurements, the units after A and C weighting are given as dBA and dBC, respectively.

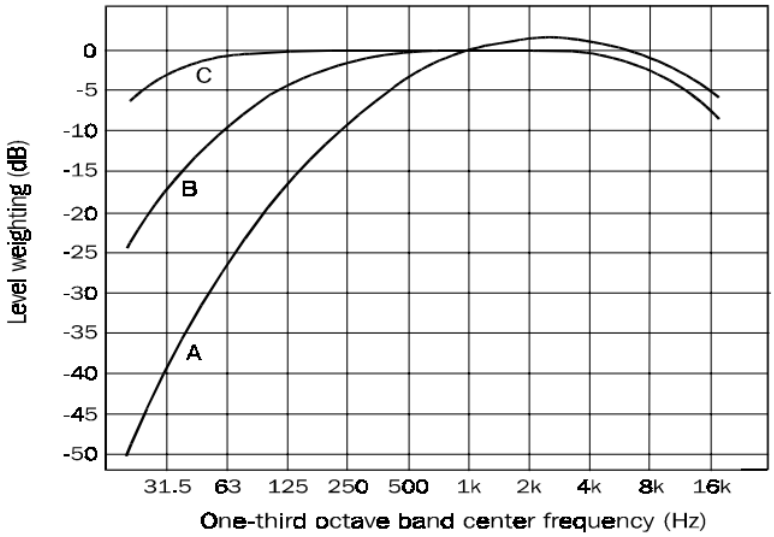

Figure 8: Different frequency weighting networks that are commonly used (Hansen, 2001).

There exists a large variety of different instruments for sound measurements. The choice of measurement instrument depends on the sound to be measured, its frequency content and its dynamic range. Sound level meters are usually simple to use with the possibility to display different parameters, such as SPL, L_{eq}, and maximum and minimum peaks.

In some sound and noise measurements, SPL values tend to vary over time. In those cases, it is convenient to measure the equivalent continuous sound level (L_{eq}), which is the constant SPL value that would result in the same total energy over a given period of time, see Figure 9. The L_{eq} value can be calculated using equation (13), where T is the measurement duration, $p(t)$ is the sound pressure and p_{ref} is the reference pressure (20 µPa) (Hansen et al., 2001).

$$L_{eq} = 10\log\left(\frac{1}{T}\int_0^T \frac{p^2(t)}{p_{ref}^2}dt\right) \tag{13}$$

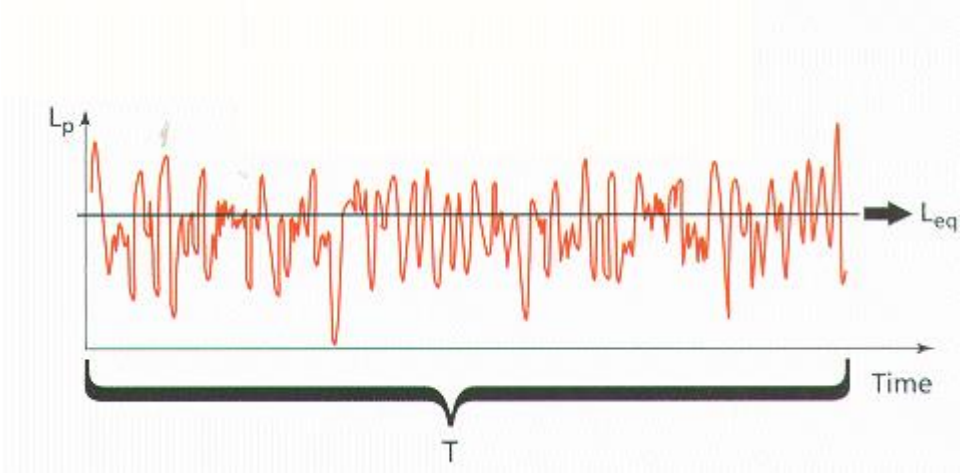

Figure 9: The L_{eq} compared to a normal SPL measurement.
(Image taken from: http://www.nonoise.org/library/envnoise/)

2.6 Noise Exposure in Daily Life

Every day, people are exposed to different types of sound and noise levels, depending on their working environment and daily activities. The type of sound, its duration and SPL can therefore vary between individuals and from day to day. Some common daily sound exposures are talk, music and noise from machinery or equipment, such as cars, airplanes and vacuum cleaners, as well as environmental sounds like wind, rain or birdsong. Daily sound and noise exposure can vary significantly between individuals and the exposure can be influenced by many factors, for example gender, residency, occupation and hobbies (Flamme et al., 2012). The typical daily noise exposure of people is not very well known even though studies have been made to try to estimate it. Those studies often focus on a single specific noise source and do therefore not provide an estimation of overall noise exposure in daily life (Neitzel et al. 2014).

According to the World Health Organization (WHO) and the US Environmental Protection Agency (EPA), a lifetime exposure of $L_{eq(24h)}$ values up to 70 dBA should not result in hearing impairments. The EPA also recommends a $L_{eq(8h)}$ level of 75 dBA (*Guidelines for community noise*; U.S. Environmental Protection Agency, 1974). In a study by Neitzel et al. (2014), performed on 45 subjects that worked as flight technicians, day care workers and office workers in Sweden, the majority of all participants exceeded the recommended $L_{eq(24h)}$ level, and the mean $L_{eq(24h)}$ value was 73.6 dBA. In a larger study by Flamme et al. (2012), performed in USA on 286 participants, an overall daily average of 78 dBA $L_{eq(8h)}$ was reported. It was stated that 65% of the women and 70% of the men exceeded the $L_{eq(8h)}$ level recommended by EPA.

3 Methods

3.1 Literature Study

A literature study was made in order to gather information in the beginning of the project. Online search engines were used to find published articles about the BCI and similar devices. These articles were also used to investigate the standard requirements for similar devices and already developed test methods.

3.2 Frequency Response Measurements

Frequency response measurements were performed, by attaching the implant on a skull simulator that simulates the impedance of a human skull and generates an output voltage that is proportional to the force being delivered by the implant. A transmitter coil was then placed over the receiver coil of the implant to establish a wireless induction link, and a 5 mm silicone was placed in between. The signal used to drive the inductive link was generated by a dynamic signal analyser, Agilent 35670A (Agilent Technologies, Inc., California, USA) and then modulated with Agilent 33220A (Agilent Technologies, Inc., California, USA) function generator. The input signal was a swept sine function from 100 Hz to 10 kHz with either a 1 or 2 V_{peak} that was amplitude modulated with a 120 kHz and a 10 V_{pp} sine wave. The principal measurement setup can be seen in Figure 10.

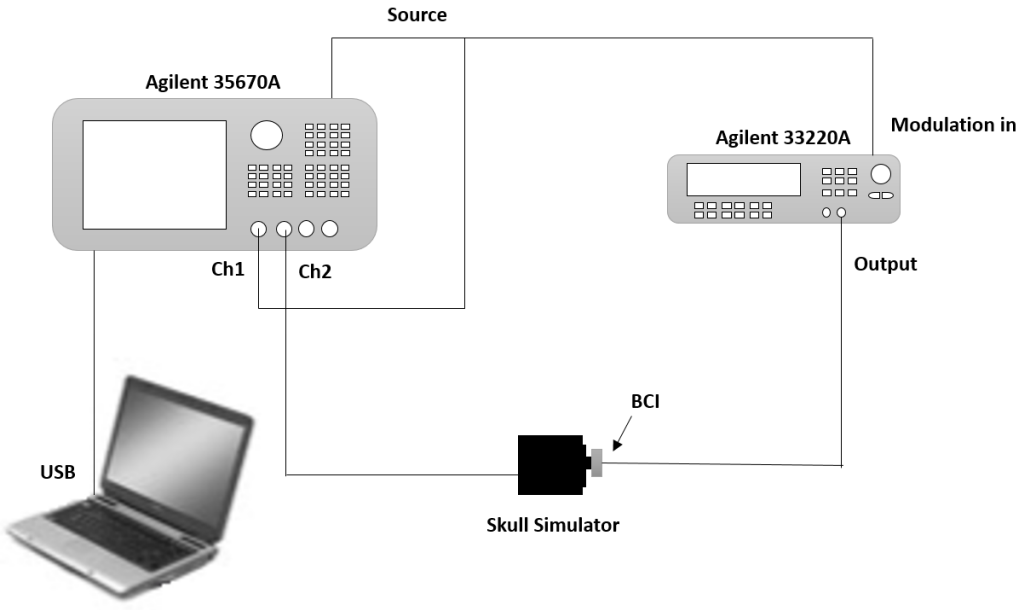

Figure 10: The principal setup used when frequency response measurements were performed

3.3 SoundCheck

The SoundCheck 12.0 software (Listen Inc., Boston, USA) was used to measure the OFL and THD of the device, and Figure 11 displays the measurement setup. During all measurements, the implant was fastened on a skull simulator that was then placed in an anechoic test chamber type 4222 (Brüel & Kjær, Sound & Vibration measurement A/S, Denmark). The SoundCheck software was used to create a swept sinusoidal wave from 100 Hz to 10 kHz at a constant SPL. The measurements were always done for three constant SPL values; 60, 70 and 90 dB SPL, where the 90 dB SPL is applied to determine the maximum power output (MPO) of the device.

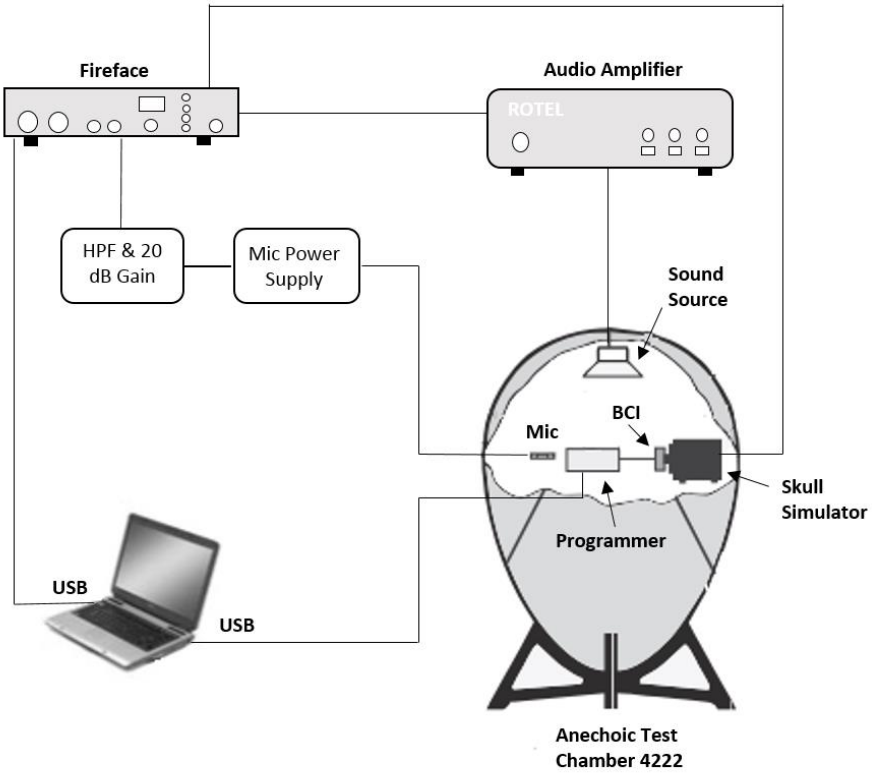

Figure 11: The setup used when performing SoundCheck measurements.

3.4 Sound Exposure Test

3.4.1 Experimental Setup

The sound exposure test was done on one complete BCI system, with the implant ready to be used for implantation and the AP programmed with normal fitting settings. A sound isolated box was constructed to store the BCI and a speaker during the test. The box was made from a cardboard box with another smaller plastic box inside, while the space between the two boxes was filled with mineral wool for sound and heat isolation. A speaker inside the box was connected to a radio outside the box which was continuously broadcasting during day-and-night. The radio was set to Swedish radio program 1 (P1), which was chosen as a sound source because it combines talk, music and other sounds that people are commonly exposed to during everyday life. There was also a 20 Watt light bulb

and a thermometer in the box in order to achieve similar ambient temperature as after implantation, which is close to 37°C. Outside the box, a dimmer was used to control the power to the lightbulb and thereby its emitted temperature. A small hole was made in the box for the neck of the Modular Precision Sound Level Meter type 2231 (Brüel & Kjær) for SPL measurements. This allows the box to be closed during the measurement. The box along with the radio, power supply and the thermometer are shown in Figure 12.

Figure 12: The box that was made for the sound exposure test.

The implant was attached on a skull simulator using a new coupling arrangement that is more stable and allows for less movement of the implant than conventionally. A 5 mm thick silicone sheet was used to act as skin between the implant and the AP. Instead of using a battery for power supply to the AP, it was connected to a 1.3 V constant DC power supply in order for it to constantly run during the experiment without a need to frequently change batteries. The skull simulator with the BCI attached to it was placed in the box in front of the speaker in a way that when the SPL was measured, it was measured next to the microphones on the AP.

When starting the experiment, baseline measurements were performed for the frequency response, THD and OFL, both when the device was at room temperature and after it had been in the box in 37°C for 4 hours. The device was then placed in the box and kept there for 5 weeks. During the first 10 days the frequency response, OFL and THD were measured on a daily basis, but later on, measurements were done on Mondays, Wednesdays and Fridays. Before these measurements, the $L_{eq(10min)}$ was measured for 10 minutes before the box was opened. Then the BCI was disconnected from the power supply and taken out of the box. The frequency response was then measured 10 minutes after the box

had been opened and the OFL and THD measurements in the anechoic chamber were performed after additional 10 minutes. During the measurements in the anechoic chamber, a battery was used to power the AP. In order to try to avoid measurement variations related to repeatedly removing and attaching the implant to the skull simulator, the implant was never removed from the skull simulator during the experiment.

3.4.2 Expected Lifetime Estimation

In order to estimate the expected lifetime of the BCI, two different methods were used. The first method was based on the difference, y, between the measured $L_{eq(10min)}$ and the $L_{eq(24h)}$, that was determined in a study by Neitzel et al. (2014). Thereby, a scaling factor, x_1, could be obtained to relate the time in the box to a time spent in the average noise exposure, which can be calculated using equation (14).

$$10log_{10}(x_1) = y \tag{14}$$

There is one additional scaling factor, x_2, that should be included. It arises due to the fact that the BCI was in the box all day long, but is only used by a patient for a part of that time every day and can be calculated using equation (15). The average usage of the BCI is believed to be very similar to the average usage of BAHA, which is 11.3 hours a day with the majority of patients using it for more than 8 hours every day (Sánchez-Camón et al., 2007; Dutt et al., 2002).

$$x_2 = \frac{24\ hours}{average\ BCI\ usage\ in\ hours} \tag{15}$$

Finally, the scaling factors were combined and used to calculate the expected lifetime of the BCI, according to equation (16).

$$Expected\ lifetime = x_1 x_2 \cdot time\ in\ box \tag{16}$$

A second approach to obtain an appropriate scaling factor was also tested. In this approach, which is only a rough estimation, it is assumed that deflections that occur at levels below 70 dBA can be considered negligible with respect to mechanical wear of the transducer. In a study by Flamme et al. (2012) about typical noise exposure, it can be seen that roughly 17% of measured $L_{eq(3.75min)}$ values are above 70 dBA. It can therefore be assumed that a patient is only exposed to the sound level in the box for about 4 hours a day. The resulting scaling factor would then be $24/4 = 6$.

3.5 Mechanical Testing

The robustness of the implanted transducer was thoroughly investigated by performing a series of mechanical investigations comprising: mechanical shock, random vibration, drop, and impact tests. The transducer and demodulation circuits were placed in a titanium case, which was then sealed in silicon as the final implant where the surface facing the bone is not covered with silicone. A receiver coil was placed on a breadboard and an external transmitting unit was

used to drive the transducer for evaluation of the frequency response before and after mechanical stress. A 5 mm silicone simulating the skin was placed between the receiver coil and the transmitting unit.

3.5.1 Mechanical Shock Test

The shock test was performed by applying a half sine pulse of 500 g over 1 ms in 5 directions as specified in AAMI CI DRAFT 0.9. A hollow aluminum rod with the dimensions 40x40x1000 mm and covered with a vibration damping material on both the inside and outside was used as a pendulum when performing the shock test. The upper part of the rod was connected to a bearing that allowed it to rotate and a potentiometer was used to measure the release angle of the pendulum rod. The transducer was fastened on a separate aluminum plate that was separated from the rod by a sheet of a vibration damping material to filter out vibrations of the rod. An extra weight was also added to the aluminum plate to improve the shape of the shock pulse. An accelerometer of type 4375 (Brüel & Kjær) with an acceleration sensitivity of 3.11 pC/g was used to measure the transducers acceleration. The signal from the accelerometer was then fed to a charge amplifier type 2651 (Brüel & Kjær) with a sensitivity of 0.1 mV/pC. Finally a PicoScope PC oscilloscope (Pico Technology, United Kingdom) was used to low-pass filter the signal and to plot the acceleration curve. The signal was low-pass filtered in order to eliminate small vibrations and the cut off frequency used was 3 kHz.

Baseline frequency response measurements were done before starting the mechanical shock test. Before performing the test on the transducer, a few test runs were done in order to calibrate the system and approximate the angle that the rod had to be raised to in order to create a pulse of 500 g over 1 ms. The transducer was then exposed to shocks in five different directions along the three mutually perpendicular axes, these directions can be seen in Figure 13. After each shock, the performance was evaluated by measuring the frequency response of the transducer. The ambient temperature in the measurement room was 24°C.

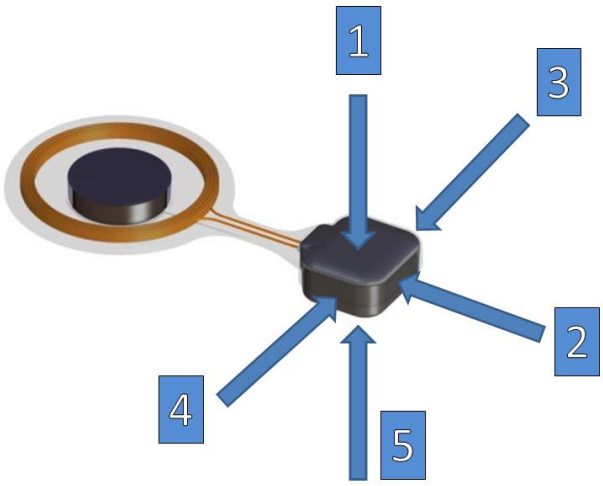

Figure 13: The directions of the shocks that the transducer was exposed to during the mechanical shock test.

3.5.2 Random Vibration Test

A dynamic signal analyser, Agilent 35670A (Agilent Technologies, Inc., California, USA) was used to generate the signal, which was fed to a LPA01 Laboratory Power Amplifier (Newtons4th Ltd., UK) that was then connected to a Mini-Shaker type 4810 (Brüel & Kjær) that produced the vibrations. An impedance head type 8000 (Brüel & Kjær), that contains an accelerometer, with a sensitivity of 36.3 pC/g, was mounted on the Mini-Shaker in order to measure the acceleration that was generated. A special fastening that was screwed on to the impedance head was used to fasten the transducer to the Mini-Shaker, the fastening can be seen in Figure 14b) - 14d). The acceleration output from the impedance head was connected to charge amplifier type 2635 (Brüel & Kjær) with a sensitivity of 1 mV/pC, which was connected to the Agilent 35670A in order to be able to analyse the signal and plot the ASD. The whole measurement setup can be seen in Figure 15.

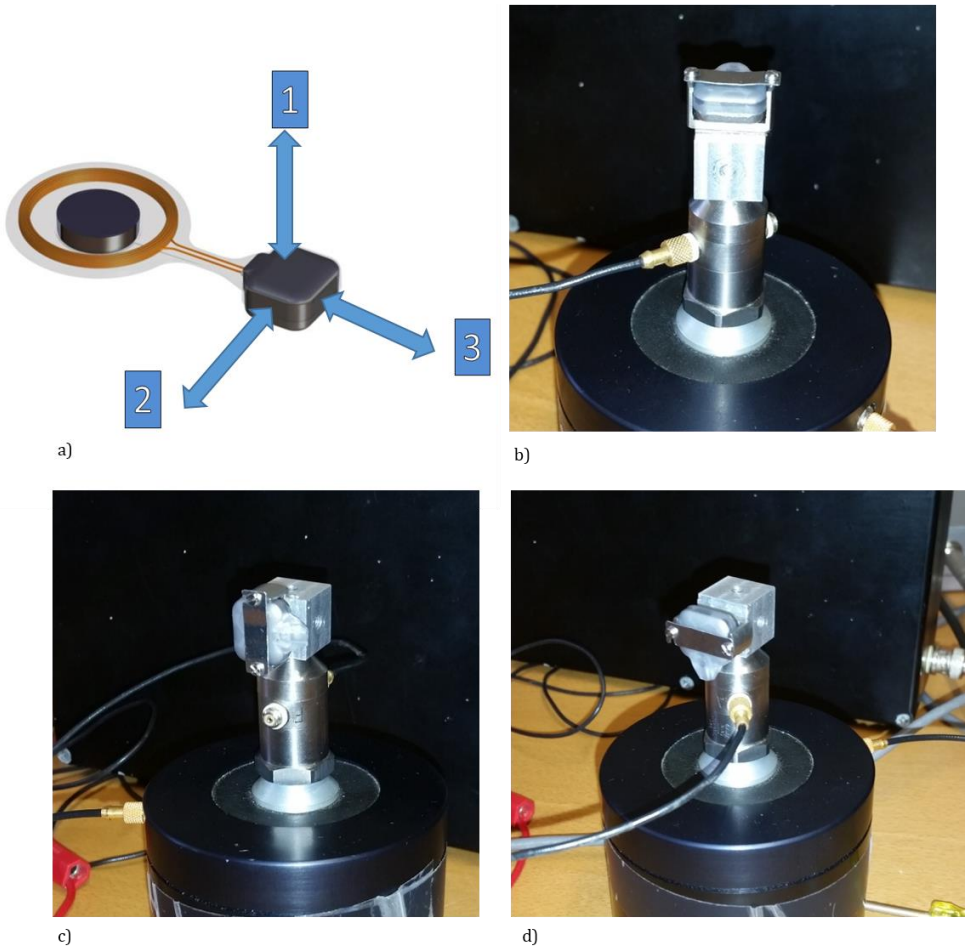

Figure 14: a) Directions that were used during the vibration test b) The transducer mounted on the mini shaker in direction 1, c) The transducer mounted on the mini shaker in direction 2, d) The transducer mounted on the mini shaker in direction 3.

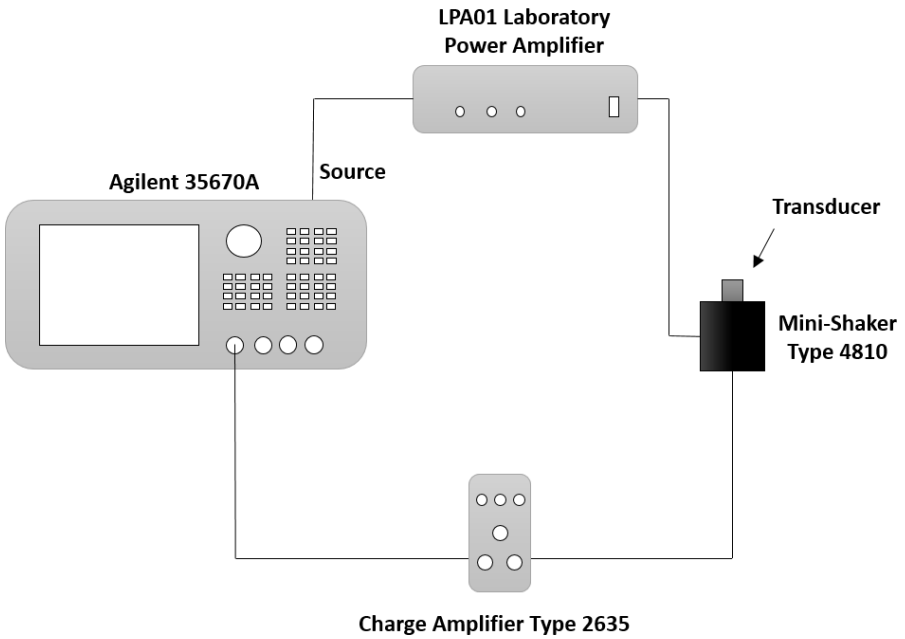

Figure 15: The measurement setup used during the random vibration test

The test was initiated with a baseline frequency response measurement of the transducer. It was then exposed to vibration for 30 minutes in three mutually perpendicular axes, see Figure 14a. Frequency response measurements were performed after vibration in each direction to determine if the vibrations had resulted in any changes. The signal that was used to produce the vibrations was a 1 V_{peak} random noise signal within the frequency range of 5 – 805 Hz, with a nearly flat ASD curve. The ambient temperature when all measurements were done was 24°C.

3.5.3 Drop Test

A pendulum rod of aluminum, similar to the one that was used in the shock test was used to simulate a fall from a 50 cm height onto an aluminum surface. The transducer was placed on a low friction floor attachment and the pendulum was then raised and released to hit the transducer. A net was used to capture the transducer and give it a soft landing after being hit by the aluminum rod.

Baseline measurement of the transducers frequency response was performed before the test was started. The transducer was hit in five different directions along the three mutually perpendicular axes; the directions used can be seen in Figure 16. After each impact, the frequency response of the transducer was measured. The test was performed using the laboratory at Oticon Medical Ekonomivägen 2, Askim, Göteborg and the ambient temperature was 21°C.

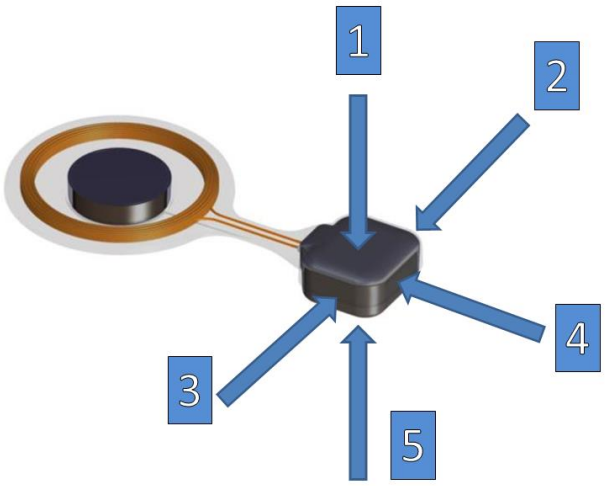

Figure 16: The directions of the impacts that the transducer was exposed to during the drop test.

3.5.4 Impact Test

A type of a vertical hammer was used to perform the impact test which was also done at Oticon Medical in an ambient temperature of 21 °C, and performed according to AAMI CI Draft 0.9. The transducer was placed on a flat rigid surface and a protective layer of 3 mm thick silicone was placed on top of the transducer. The energy of the desired impact was 2.5 J and with a metal ball of 1.622 kg, this results in a height of 15.7 cm, according to equation (11). The metal ball was

therefore elevated to 15.7 cm and then dropped on the transducer with the silicone in between. Only one impact was produced and its direction can be seen in Figure 17. After the impact test, the frequency response of the transducer was measured.

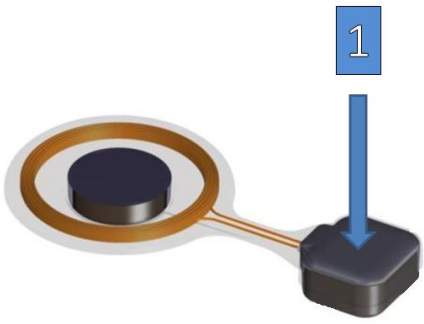

Figure 17: The direction of the impact during the impact test.

Results

3.6 Sound Exposure Test

When first starting the sound exposure test, it was noticed that the implant performance was sensitive to the temperature in the box when it was increased from room temperature (20-23°C) to the assumed operation temperature (36-38°C). It was therefore decided to investigate that further by keeping just the implant without the AP in the box for 15.5 hours, which was believed to be enough time for the implant to warm up, and then measure its frequency response every hour while it was cooling down. It was discovered that the ambient temperature affects the frequency response of the implant. After the implant had been in 36.8°C in the box for 15.5 hours the lower resonance peak decreased from 871 Hz to 794 Hz and the higher one decreased by 2 dB and shifted from 5754 Hz to 5495 Hz. As the implant cooled down its frequency response changed and successively got closer to the baseline measurement. It mainly changed in the first hours after taken out of the box and then slowed down. After cooling down for 68 hours it had almost completely recovered, see Figure 18.

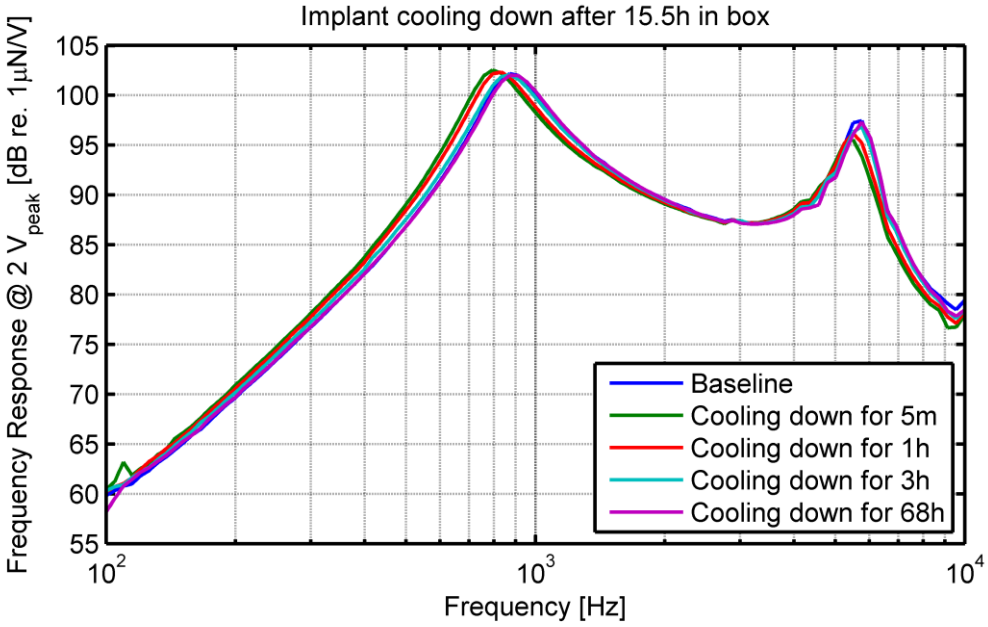

Figure 18: The frequency response of the implant 5 minutes, 1 hour, 3 hours and 68 hours after it was taken out of the box, where it had been for 15.5 hours in a temperature of 36.8°C

During the 5 weeks that the BCI was in the box, the average temperature when measurements were made was 37.5°C with a standard deviation of 0.8°C. The average measured SPL in the box was 78.2 dBA $L_{eq(10min)}$. When the BCI had been in the box for 3 days in an average temperature of 37.5°C there was a shift in the frequency response when the upper resonance frequency shifted from 5495 Hz to 5248 Hz. This change is believed to be due to the temperature in the box rather than the sound exposure. After day 3, the higher peak remained at 5248

Hz and no considerable difference was seen. Figure 19 compares the frequency response before the sound exposure test was started and after the BCI had been in the box for 5 weeks.

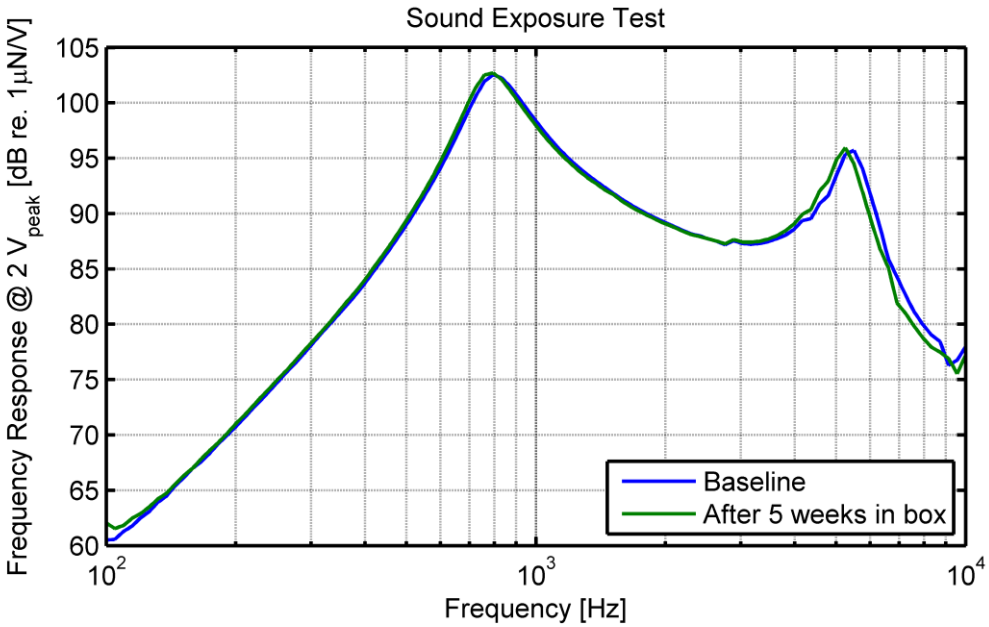

Figure 19: The baseline frequency response of the implant before it was exposed to any sound compared to the frequency response after the implant was in the box for 5 weeks.

The 5 weeks in the box are not believed to have affected the THD of the BCI. It is still very low for 60 and 70 dB SPL and a little higher for 90 dB SPL when the device is saturated. During some measurements, some decrease was observed in the OFL and a considerable increase in the THD, this was due to the battery running out and when the battery had been replaced this could no longer be observed. The OFL and THD before the test was started and after the BCI had been in the box for 5 weeks are shown in Figure 20 and Figure 21, respectively. When comparing the THD and OFL before and after the test, it can be seen that there is some difference between them, especially in the THD and the OFL for 90 dB SPL, these are minor changes that are believed to be caused by the battery rather than the sound exposure.

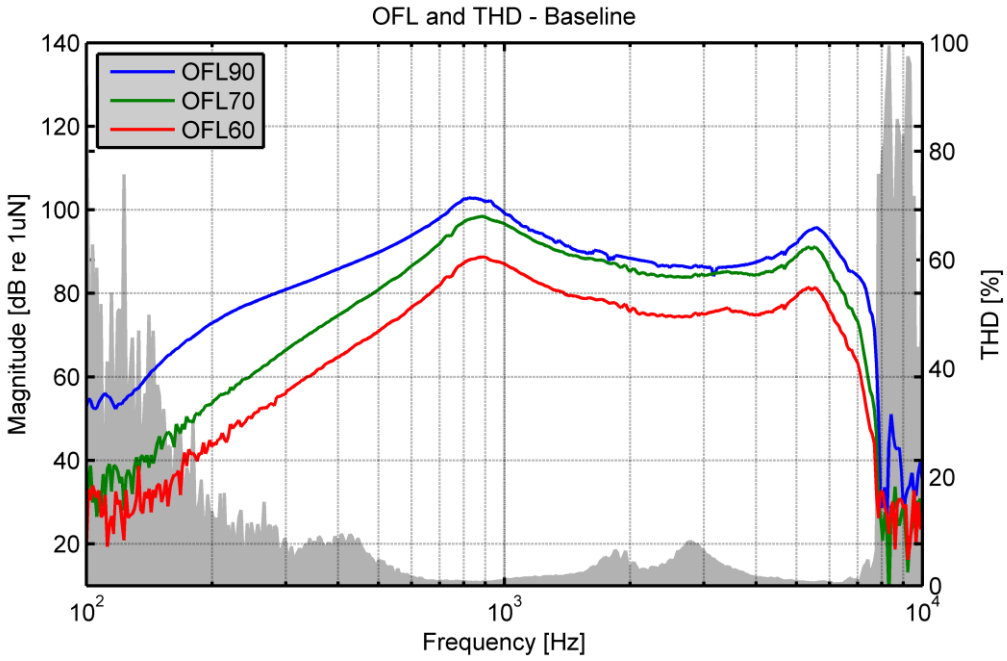

Figure 20: The OFL for 60, 70 and 90 dB SPL and THD for 70 dB SPL before the sound exposure test was started.

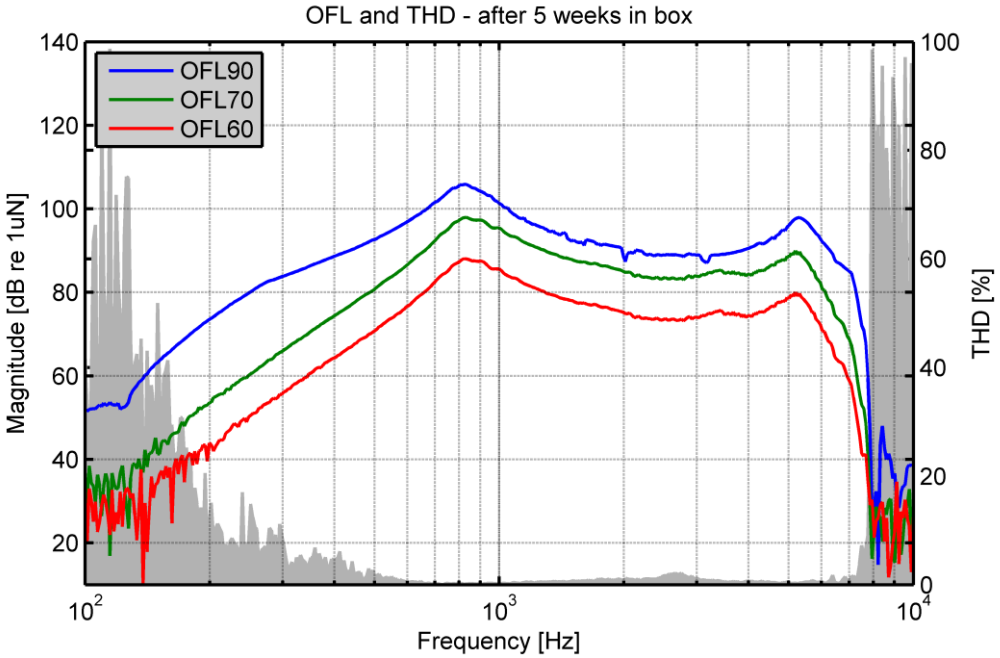

Figure 21: The OFL for 60, 70 and 90 dB SPL and THD for 70 dB SPL after the test had been conducted for 5 weeks.

During the sound exposure test, the average $L_{eq(10min)}$ value was 78.2 dBA and the first scaling factor, x_1, used when calculating the expected lifetime was therefore 2.9 according to equation (14). Hence, 24 hours in 78.2 dBA would then correspond to approximately 69 hours in 73.6 dBA. The second scaling factor, x_2, is 2.1 according to equation (15). Thus, by multiplying the two scaling factors, the total scaling factor becomes 6.1, which is close to 6, i.e. the scaling factor that was obtained using the second method. The minimum expected lifetime of the BCI with respect to the follow-up time of 5 weeks is therefore 30 weeks or 7.5 months, according to equation (16).

3.7 Mechanical Testing

3.7.1 Mechanical Shock Test

During the mechanical shock test, pulses with an acceleration of about 500 g and a duration of 1 ms (Figure 22) were applied to five different sides of the transducer, see Figure 13. After the mechanical shock test had been performed, no considerable difference could be seen in the frequency response of the transducer. Baseline frequency response measurements done before the test showed resonance peaks at 794 Hz and 5495 Hz with amplitudes of 104.2 and 99.1 dB relative to 1μN/V. After the shock test, the resonance peaks remained the same and there was no difference between the two curves at 2 kHz. Figure 23 illustrates the frequency response before and after the test was performed.

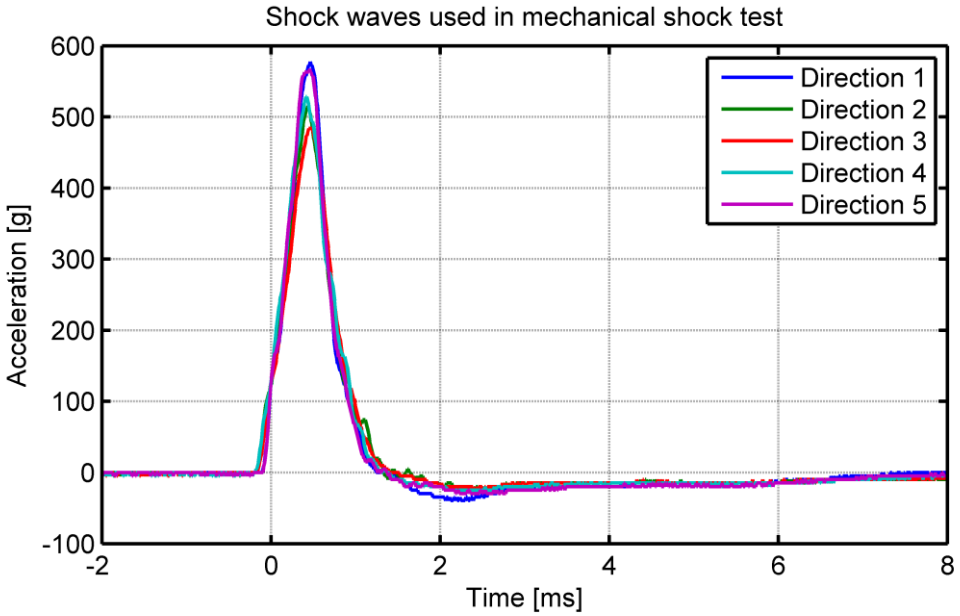

Figure 22: Shock waves with an acceleration peak of approximately 500 g that were used in the shock test.

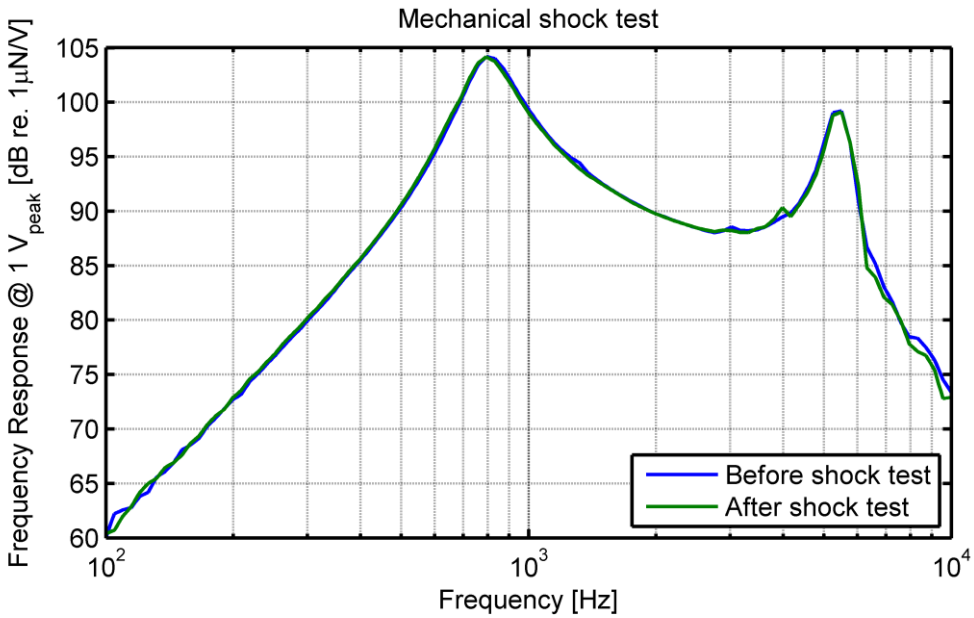

Figure 23: The frequency response of the transducer before and after mechanical shock test in five directions.

3.7.2 Random Vibration Test

A random noise signal was used to create the vibrations in the Mini-Shaker and the resulting acceleration measured at the impedance head can be seen in Figure 24. The acceleration spectral density (ASD) curve of the measured acceleration signal can be seen in Figure 25. Because of limitation of the Mini-shaker and the Agilent 35670A, the signal used was not in total accordance with AAMI CI DRAFT 0.9, which states that the signal should have a flat ASD curve of 0.7 $(m/s^2)^2/Hz$ from 5 to 500 Hz. The signal used was within 5 to 805 Hz and had the same overall r.m.s. acceleration power as the signal specified in the standard and only had a slightly different ASD.

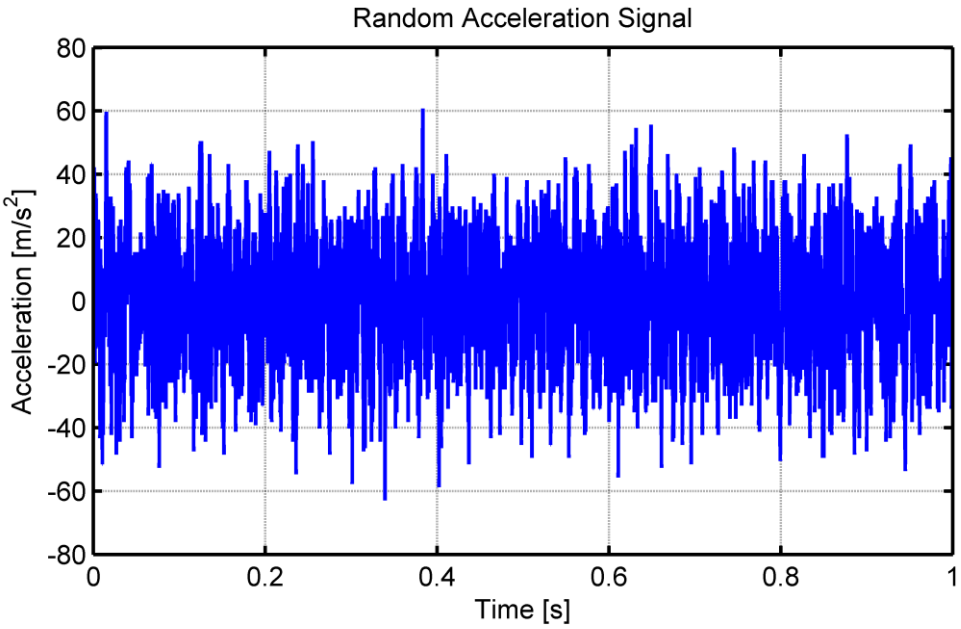

Figure 24: The time acceleration signal used in the vibration measurements.

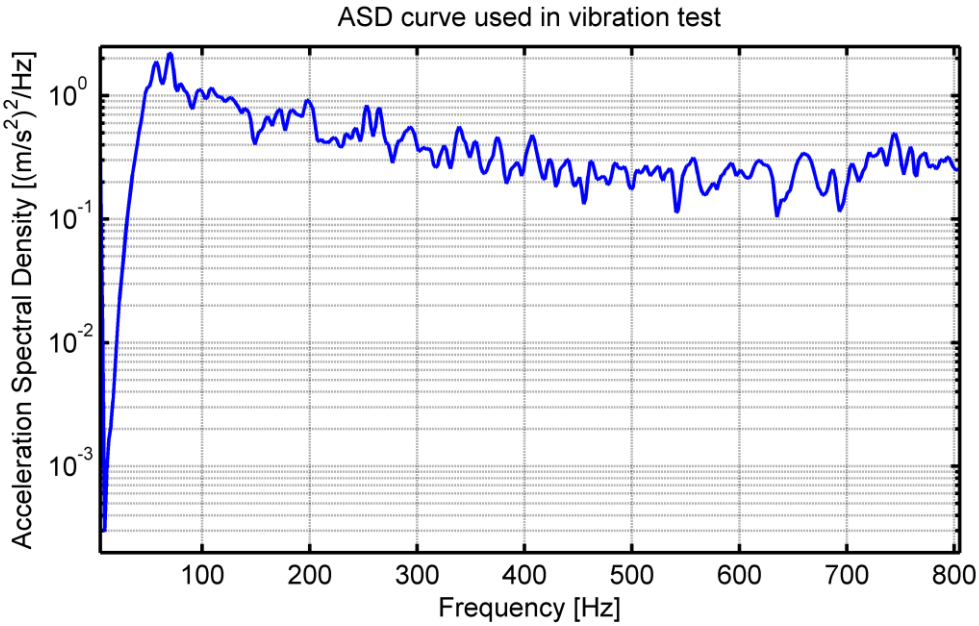

Figure 25: The ASD curve of the acceleration signal.

Figure 26 shows the transducers frequency response after the vibration test had been performed as well as the baseline frequency response measured just before the test was started. No significant difference can be seen between the curves. Both the baseline measurement and the measurement after the vibration test showed two resonance peaks; 104.3 dB re. to 1µN/V at 794 Hz and 99.2 dB re. to 1µN/V at 5248 Hz. The amplitude at 2 kHz was 89.8 dB re. to 1µN/V on both curves.

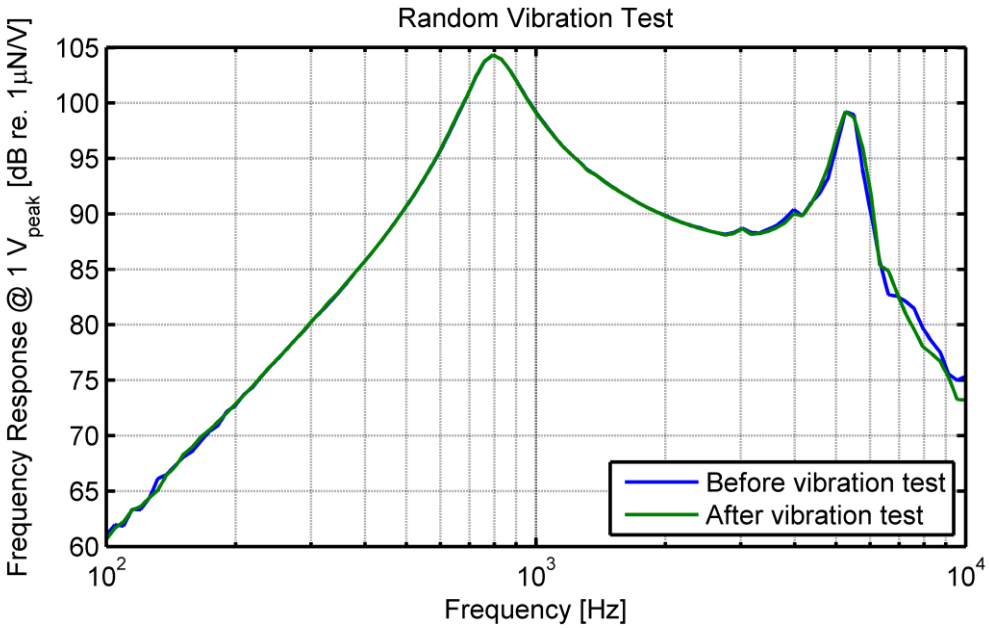

Figure 26: The frequency response of the transducer before and after the vibration test in all directions.

3.7.3 Drop Test

Figure 27 shows the frequency response of the transducer before and after drop from 50 cm in each direction. It was found that both the amplitude and the frequency position of the resonance peaks changed between all curves. The frequency response before and after the drop test in all five directions is shown in Figure 28. It can be seen that the lower resonance peak shifts from 832 Hz to 724 Hz and the peak decreases by 1.1 dB, and the higher resonance shifts from 5495 Hz to 5012 Hz and the peak decreases by 4.1 dB. This corresponds to a 12% decrease in the frequency of the lower resonance peak and 9% decrease in the higher one. However, there is no considerable difference at 2 kHz for any of the curves.

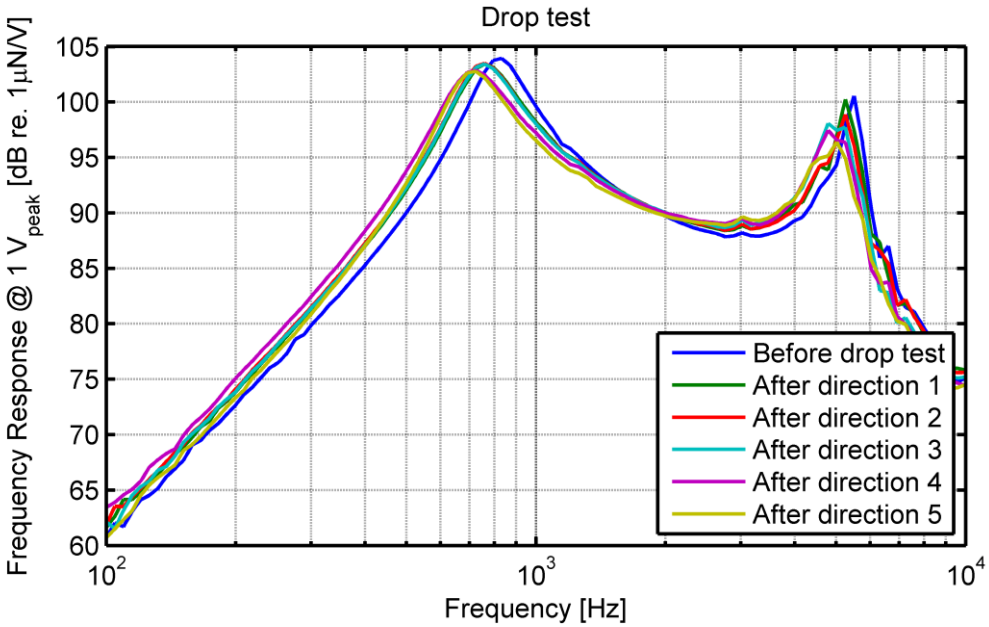

Figure 27: Comparison of the frequency response of the transducer before the drop test was performed and after drop in each direction.

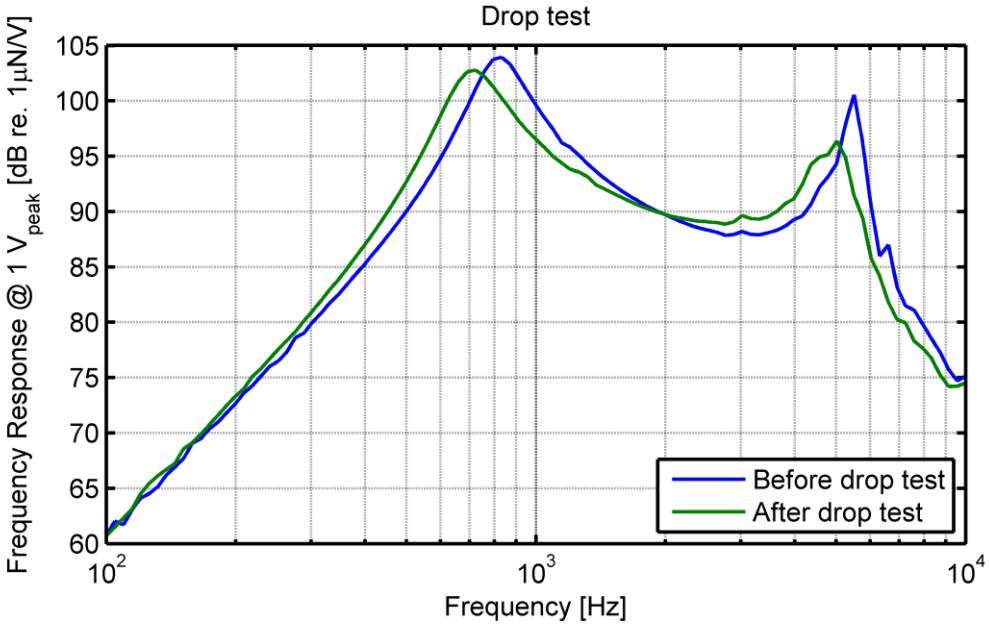

Figure 28: The frequency response of the transducer before and after the drop test in all directions.

3.7.4 Impact Test

The impact test with 2.5 J was performed directly after the drop test with the results as shown in Figure 29. In this measurement, the curve after the drop test was used as baseline to make a relative comparison. The lower resonance peak is the same and there is no considerable difference at 2 kHz between the curves but there is however a 441 Hz decrease in the higher resonance frequency as it shifts from 5012 Hz to 4571 Hz.

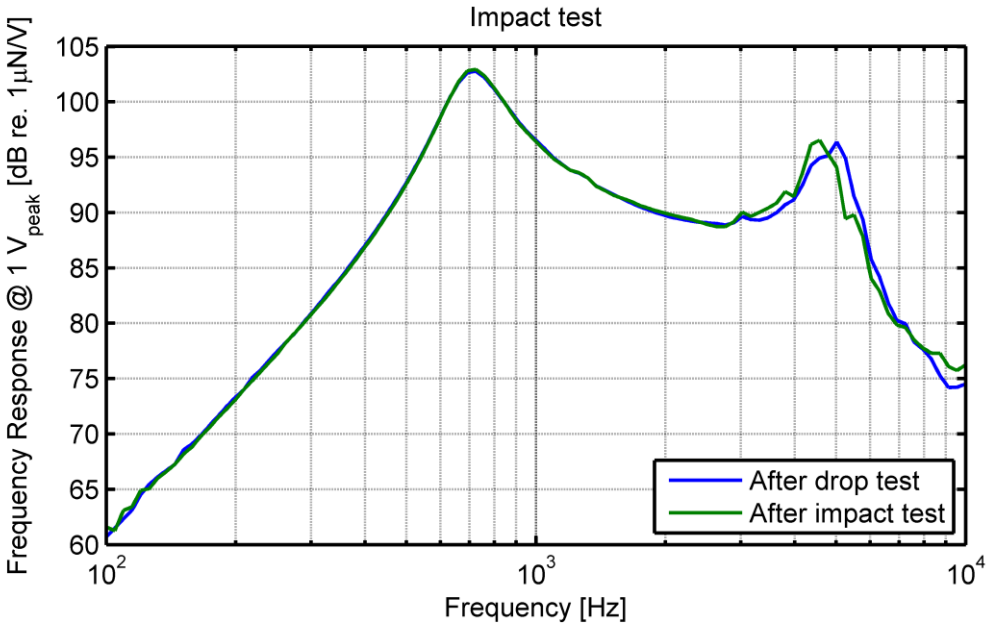

Figure 29: The frequency response of the transducer before and after the impact test.

3.7.5 After All Testing

The frequency response measurements after the mechanical shock and vibration tests were done in ambient temperature of 24°C (it just happened to be quite warm in the relatively small lab at Chalmers due to all the equipment running). The frequency response measurements after the drop and impact tests were done in ambient temperature of 21°C. Since the sound exposure experiments have shown that temperature affects the frequency response of the transducer, the frequency response after both drop and impact tests was measured again in 24°C after it had recovered for 43.5 hours. Figure 30 summarises the results from all the tests by comparing the frequency response before and after all the tests, measured under the same conditions at 24°C. The lower resonance frequency changes from 794 Hz to 724 Hz and decreases by 1 dB and the higher resonance peak changes from 5495 Hz to 4786 Hz and decreases by 0.7 dB. There is no difference in the frequency response at 2 kHz before and after all the tests.

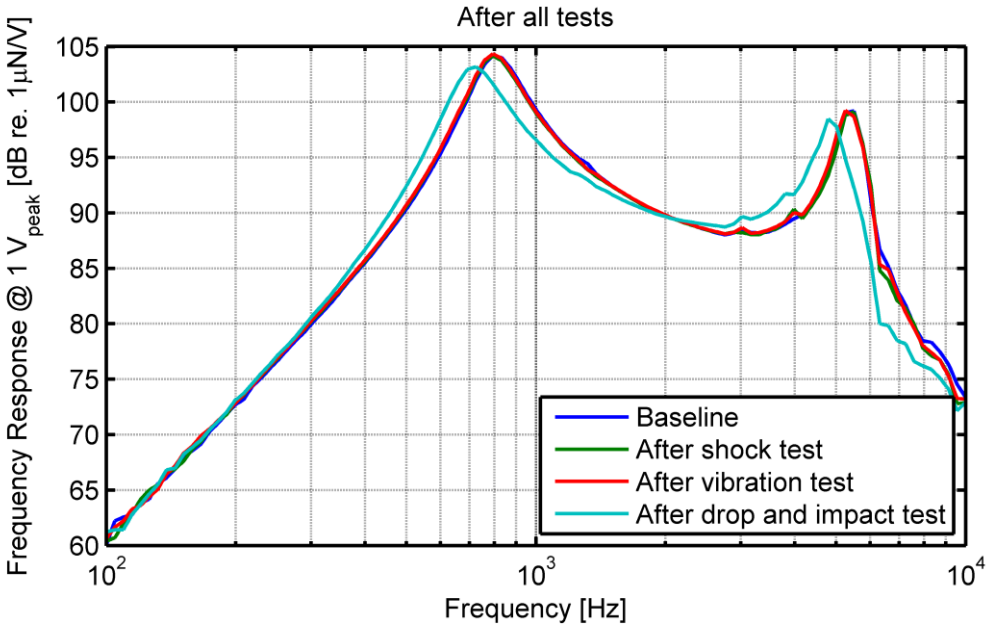

Figure 30: The frequency response of the transducer after all test compared to the baseline measurement.

4 Discussion

4.1 Sound Exposure Test

As expected, the accelerated sound exposure during the relatively limited time of 5 weeks does not affect the performance of the BCI, since there is no considerable difference in the FRF, MPO or THD before and after the test. During the first week of measurements, some changes were seen in both the MPO and THD. A minor decrease was observed in the MPO and a substantial increase in the THD. The THD for example increased from 8% to 38% at 2754 Hz for 70 dB SPL. However, when the battery in the AP was replaced, these changes were no longer observed. The BCI performance was thereby found to change as the battery started to run out, especially in terms of THD.

The ambient temperature appears to affect the performance of the device since the two resonance peaks decrease in frequency as the temperature increases, see Figure 18. According to the manufacturer of the damping material used in the transducer, it becomes softer when the temperature increases, which means that the compliance of the material increases. From eq. (1) it can be seen that an increase in the compliance leads to a decrease in the resonance frequency, which is exactly what was experienced during the test. It was also observed that when the temperature decreases again, the frequency response recovers and reaches its original shape. This means that the changes due to temperature were only temporary. Also, in the real case when the implant is worn by the patient, the temperature will be relatively stable so the temperature dependence will most likely not have any clinical effect. On the other hand, using a damping material will most likely have a smoothing effect of all resonance peaks and may therefore also prolong the lifetime of the implant and also reduce "ringing" after transients and improve the stability margins.

The target temperature in the box during the accelerated lifetime test was the temperature of the human body and varied within the range of 36.1 – 39.1°C, except for one day when it temporarily decreased to 27°C. This temperature range was stable enough to not affect the measurements. There was a minor shift in the frequency response after 3 days in the box that is believed to be caused by the implant warming up, after that the frequency response stabilised and no considerable change was observed within that temperature range.

A new fastening to the skull simulator was used for the first time in this experiment. It allows for less fixation variability than the one previously used and therefore eliminates, at least partly, fastening errors and improves repeatability. It was observed that the frequency position of the resonance peaks depends on how tight and centred the implant is attached to the skull simulator, and the tightening of the screw was therefore not altered during the experiment.

When calculating the expected lifetime of the BCI it is assumed that the $L_{eq(24h)}$ in the box does not differ much from the average measured $L_{eq(10min)}$ value. This is believed to be true since the measurements were done in different times during

the day and the sound level was not changed during the test. Therefore, the average $L_{eq(10min)}$ (78,2 dBA) in the box during the sound exposure test is used directly in calculations.

Both approaches used to obtain the scaling factor for the expected lifetime calculations give a scaling factor of 6, which suggests that the lifetime is at least 7.5 months. However, it is very likely that the device has a much longer lifetime but due to time limitations of this thesis it cannot be evaluated at this time. The sound exposure test should therefore be continued until the device fails in order to investigate its real lifetime.

4.2 Mechanical Testing

When observing the results of both the mechanical shock and random vibration test (Figure 23 and Figure 26, respectively), no difference can be seen in the FRF before and after each test. The transducer is therefore assumed to have passed both tests. However, there is a slight difference in the high frequency resonance after the shock test and before the vibration test, which was done one day after the shock test. This is a minor decrease of 247 Hz, and since there is no difference in the performance immediately after either test was performed, this shift is not believed to be caused by the tests, but rather by temperature changes, attachment to the skull simulator or other external influences.

After the impact test was performed, a minor change was seen in the transducer's FRF (Figure 29). However, it is very probable that this change is too little for the patient to notice any difference in the device's performance. When evaluating the result of the impact test, it should be taken into consideration that it was done in accordance with a standard for cochlear implants which specifies that the transducer should be covered with 3 mm of silicone for protection. However, it is most likely that the patient's skin is thicker than 3 mm and the transducer is therefore better protected, as it was shown by Raine et al. (2007) that the skin flap thickness six months after surgery of the cochlear implant patients is reduced to 5 mm. Furthermore, the BCI transducer is also protected by the pinna and the fact that it has a low profile.

The drop test introduced a 108 Hz and a 1.1 dB decrease in the low resonance peak and a 483 Hz and 4.1 dB decrease in the high one, which is more than was observed for the other tests. Again, it is not likely that the patient would notice the difference in the high resonance peak and the difference in the low one could be accounted for by refitting of the device. These changes are thus not considered severe. Also, there are some doubts about using aluminum as strike surface of the transducer casing when performing the drop test. The present set-up was developed for the BAHA, and generates a high acceleration peak during impact. This might not be a problem if hitting a device with a plastic housing around the transducer like in the BAHA, or if the impact is in a direction where the transducer for generic reasons is not susceptible to these impacts. However, this high acceleration during impact is not realistic for the BCI transducer. This is especially true when the implant is safely installed in a patient where already a couple of ten g:s are deadly, which is quite far from the couple thousand g:s that this test is impacting with. Therefore it is believed that the test used for the

BAHA should not be used for the BCI implant, but due to lack of time in this master thesis project, this procedure was used.

Only minor changes were observed in the FRF of the transducer, and since there is no considerable change in the FRF at 2 kHz, it is almost certain that the electromagnetic motor was not affected by the tests. The fact that there was no major change in the performance of the BCI during the test indicates that there is not a systematic failure in its design. If such a failure would exist, it would affect all transducers produced and would most likely have been revealed during some of these mechanical tests. However, this statement requires further testing of more devices.

During the FRF measurement, the transducer was attached to the skull simulator using a coupling that is slightly less stable than the one that was used during the sound exposure test. The transducer was always removed from the skull simulator during tests and then fastened again for FRF measurements, which might have introduced a small difference in the results. This variability was not objectively measured, but is considered to be minor, especially since care was taken to attach the transducer to the skull simulator in the same way for all measurements. Some changes in the FRF might also be due to a difference in the ambient temperature, which was 24°C for the mechanical shock and random vibration tests but 21°C for the drop and impact tests. If for example the resonance peaks before the drop test are compared to the peaks after the vibration test there is a slight increase in frequency of both resonance peaks, even though the transducer just rested between the two tests. This difference is probably caused by the ambient temperature which decreased by 3°C between the tests. This has to be taken into consideration when comparing the FRF after the tests. However, since the ambient temperature will be quite stable after implantation, these changes, which are most likely due to temperature, are believed to be minor.

When comparing the frequency response of the transducer immediately after the impact test, and after it had rested for 43.5 hours in a temperature of 24°C, there is a change in the high resonance peak. After the impact test, it was 96.5 dB relative to 1μN/V at 4571 Hz and after resting for 43.5 hours it was 98.5 dB relative to 1μN/V at 4786 Hz. Figure 31 compares the frequency response before and after the drop test, after the impact test and after the transducer has rested for 43.5 hours. As can be seen in that figure, the high frequency resonance is increasing both in amplitude and frequency and therefore getting closer to its original position and the transducer recovers from overstressing in the spring material. This change is not believed to be caused by temperature, since it is expected that the frequency decreases as the temperature increases.

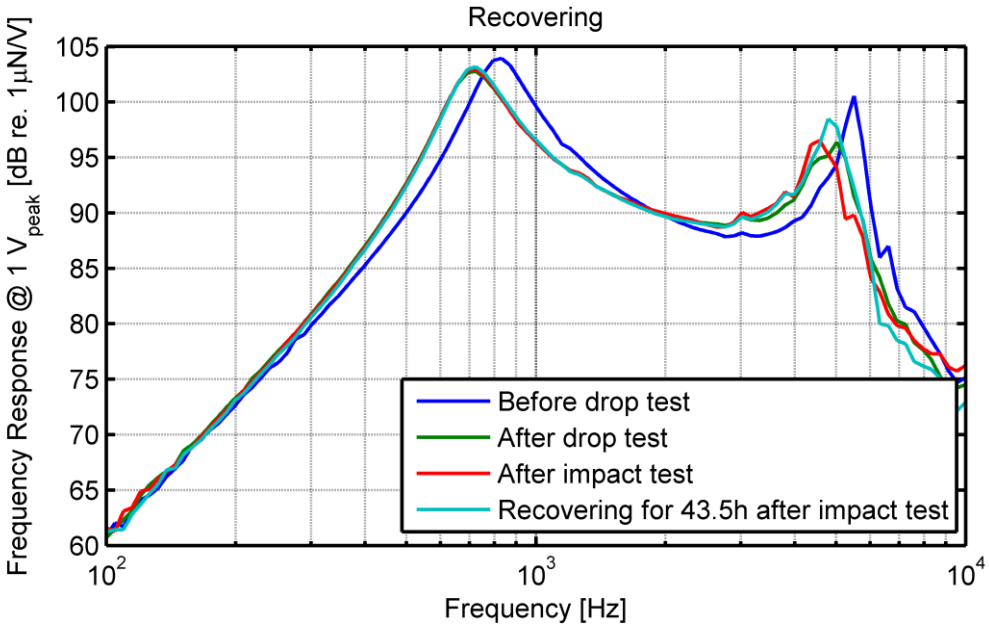

Figure 31: Comparison of the transducers frequency response before and after the drop test, the impact test and after it was allowed to rest for 43.5 hours.

5 Conclusion

The accelerated sound exposure test, which is ongoing until an expected failure occurs in the future, indicates so far that the lifetime of the BCI is at least 7.5 months. This evaluation is based on the current follow up time of the experiment during 5 weeks. Most likely, the lifetime of the device is much longer, and the sound exposure test should be continued until the device fails in order to obtain the actual lifetime of the device.

Only minor effects are seen in the performance of the separate transducer after the mechanical shock, random vibration, impact and drop test. Thus the transducer is considered to have passed all tests. The series of mechanical tests performed indicates that there is no systematic weakness in the transducers design and that it is safe with respect to mechanical stress that can occur during implantation or under conditions of normal use. It is however recommended that a study will be performed on a larger number of transducers in order to obtain more statistically reliable results.

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