CHALMERS
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# Measurement Set-up for Audibility Verification of Bone Conduction Devices using Skin Microphone

Master's thesis in Biomedical Engineering

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Cover: Measurement Set-up for Audibility Verification of Bone Conduction Devices using Skin Microphone.

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# Abstract

Bone conduction devices (BCDs) provide hearing rehabilitation to patients with impaired hearing by transmitting vibrations to their cochleae through the skull bone. The verification of the audibility of speech of BCDs has been a challenge for many years. Hence, this thesis deals with a novel method for objective measurement of audibility in BCDs in-situ using a skin microphone, developed by Hodgetts et al. (2018). This method was also verified by audibility measurements using a skull simulator and an artificial mastoid as load. The study was performed on five subjects with normal hearing wearing a skin-drive BCD placed on the skin over the temporal bone. The skin microphone was placed on the forehead in the middle between the hairline and the eyebrows using a soft band with some additional sound insulation. Five different power spectrum measurements were performed from the skin microphone: sound field hearing thresholds and maximum power output (MPO) using warble tones, International speech test signal (ISTS) at three sound levels, noise floor and by-pass leakage of sound. The audibility of the speech signal is defined as the amount of the speech spectrum falling in the dynamic range, that is, between the thresholds and the MPO. The skin microphone, the hearing device, and the reference microphone were finally removed and retested five times to establish the ISTS 65 dB SPL test-retest variability. Similarly, a test-retest of the intra-subject variability was performed with all the equipment in place. The same experimental set-up and protocol was followed for the skull simulator and the artificial mastoid.

The skin microphone's electrical output in terms of power spectrum was referred to dB relative to 0.01 $mV_{rms}$ to give convenient values. The average ISTS at 65 dB SPL for five subjects, was found to be in the dynamic range and thus audible, except for the highest frequencies. This was also observed in the verification measurements using the skull simulator and the artificial mastoid. For all three methods, in order to simplify the comparison, all power spectra at audiometric frequencies were normalized to the hearing thresholds being 0 dB. The overlapping normalized results from ISTS at 65 dB SPL using the skin microphone method, the skull simulator and the artificial mastoid, respectively, verifies the accuracy in terms of audibility of this new method. This novel method based on hearing thresholds, MPO and speech mapping using the skin microphone's electrical output can be used for audibility verification and a tool for fitting procedures in all types of BCDs but it needs to be verified also on real patients.

Keywords: Bone conduction device, Audibility, Skin Microphone, Sound pressure level, Verification.

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Moksha Caveramma Mechanda, Gothenburg, May 2021

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# Abbreviations and Acronyms

| | |
|---|---|
| AC | Air Conduction |
| AM | Artificial Mastoid |
| BAHA | Bone Anchored Hearing Aid |
| BC | Bone Conduction |
| BCD | Bone Conduction Device |
| BCDs | Bone Conduction Devices |
| BCI | Bone Conduction Implant |
| BEST | Balanced Electromagnetic Separation Transducer |
| DR | Dynamic Range |
| eSPL-o-gram | Threshold, speech and MPO, as output voltage level dB re 10$\mu$ volt |
| FFT | Fast Fourier Transform |
| FL | Force Level |
| FL-o-gram | Threshold, speech and MPO, as output force level dB re 1$\mu$ Newton |
| HL | Hearing Level |
| ISTS | International Speech Test Signal |
| LTASS | Long Term Average Speech Spectrum |
| MFO | Maximum Force Output |
| MPO | Maximum Power Output |
| OFL | Output Force Level |
| PTA4 | Four-frequency Pure Tone Average |
| RBM | Real Bone Measurement |
| re | Relative |
| REM | Real Ear Measurements |
| SD | Standard Deviation |
| SPL | Sound Pressure Level |
| SS | Skull Simulator |

# 1
# Introduction

## 1.1 Background

The human ear is divided into outer ear, middle ear, and inner ear, and accordingly, hearing loss is categorized into three types: conductive, sensorineural, and mixed hearing loss. Conductive hearing loss occurs when there is a problem transferring sound waves through the outer and middle ear, and sensorineural hearing loss occurs when there is a damage in the inner ear, whereas, mixed hearing loss is a combination of the two [1]. According to World Health Organization, there are 1.5 billion people in the world who live with some degree of hearing loss and by 2050 nearly 2.5 billion people are projected to have the same condition [2]. Until 2018 about one-third of people with hearing loss wore hearing aids and it was expected to increase every year [3]. As of 2015, Swedish Association of Hard of Hearing People estimated 1.4 million hard of hearing people in Sweden [4].

We humans hear sound through two pathways: via our eardrums (air-conducted) and via our skull bone (bone-conducted). Normally the sound we hear is through air conduction (AC), which means, the eardrums convert sound waves into vibrations that are received by the cochlea, also known as the inner ear, and transmit it to the brain. However, bone conduction (BC) bypasses the eardrums by directly transmitting vibrations to the cochlear through the skull bones [5]. This is possible with the help of bone conduction hearing devices.

Bone conduction devices (BCDs) provide hearing rehabilitation to patients with conductive or mixed hearing loss. It is classified as either “direct-drive” or "skin-drive” BCDs. The direct-drive BCDs transmit vibrations directly to the bone and the skin-drive BCDs transmit vibrations through the intact skin. The direct-drive devices are divided in percutaneous and active transcutaneous devices, while the skin-drive devices are divided in conventional and passive transcutaneous devices [6], as shown in figure 1.1.

The Bone Conduction Implant (BCI) is an active transcutaneous direct-drive BCD, currently undergoing clinical trials [7]–[10]. It has an external audio processor transmitting electromagnetic signals and an internal implant which consists of a retention magnet, a receiving coil, a demodulator and a balanced electromagnetic separation transducer (BEST) [7]. This electromagnetic signal is transmitted through the skin via an inductive link to the implanted transducer. Another example of a BCD which is commonly used is the bone anchored hearing aid (BAHA), a percutaneous direct-drive BCD that is well established on the market [6], [11], [12]. BAHA has a sound processor that is attached to the skull bone via a skin penetrating abutment to a titanium screw. It stimulates the bone directly unlike the skin-driven BCDs. Figure 1.1 shows the categorization of BCDs, and Figure 1.2 shows some examples of bone conduction hearing aids.

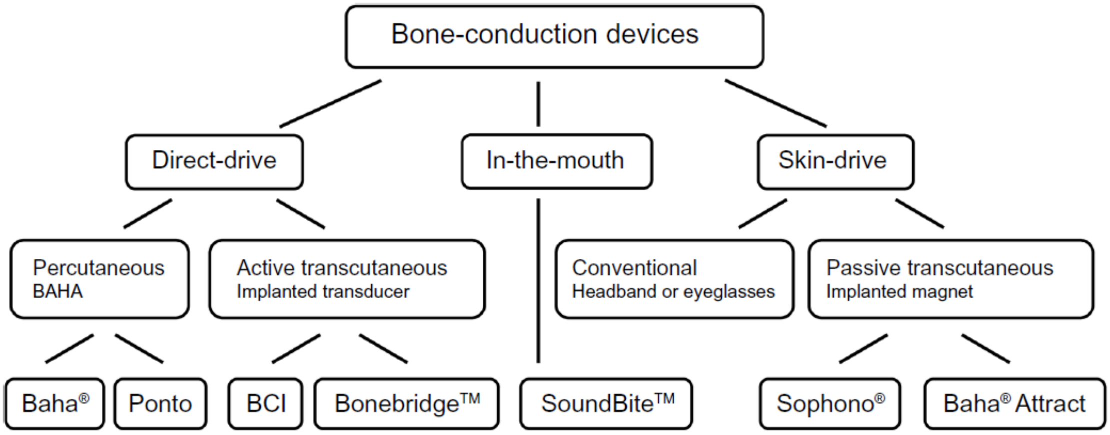


**Figure 1.1:** Categorization of bone conduction devices [6]. Baha: bone-anchored hearing aid; BCI: bone-conduction implant.

Verification of hearing aid fitting is performed to ensure that the hearing aid is operating appropriately. It provides the clinicians to suggest an optimally or better fitted hearing aid to their patients and promote greater satisfaction. The verification of conventional hearing aids are usually performed either through probe tube microphone systems or AC coupler microphones [13]. The commonly performed probe microphone measurements is the real-ear measurement (REM). During REM, the probe microphone is inserted into the ear canal to measure the sound pressure level (SPL) reflected by the eardrum, for example - to conversational speech in quite, and determine the precise level of amplification needed at every frequency band in order to achieve the best hearing level for every hearing aid user [14]. This method along with a series of transforms is used to assess the actual output of the hearing aid in dB SPL. Therefore, the fundamental goal of a hearing aid fitting is to maximize the audibility of useable speech. However, verification of the fitting of BCDs has always been a challenge. Clinicians still fall back on the use of aided sound field thresholds to assess the fitting of the BCDs, although they provide limited information. Apart from that, there are different successful approaches and ongoing studies on the verification of fitting of BCDs in terms of the audibility of speech, dynamic range (DR), and the input-output characteristics of the BCD, which will be discussed in the next chapter; One such approach is investigated in this thesis.

**Figure 1.2:** Few examples of bone conduction devices (BCD) [6]. (a) Conventional BCD (top left); (b) Passive transcutaneous skin-drive BCD (top right); (c) Percutaneous direct-drive BCD (bottom left); (d) Active transcutaneous direct-drive BCD/BCI (bottom right).

## 1.2 Aim of thesis

The aim of the thesis is to objectively measure the audibility of a BCD in-situ using a skin microphone. The objectives of the thesis are as follows:

- To investigate the validity of using the skin microphone in a REM (could also be called real bone measurement (RBM)) in-situ headset during BCD audibility measurement and verification.
- To compare the above mentioned measurements with the BCD audibility measured using a skull simulator and an artificial mastoid.

## 1.3 Research Questions

- Elaborate on the validity of using the skin microphone in the RBM in-situ system.
- Can the sound insulated skin microphone be used as a better or an alternative approach to verify the audibility of BCDs when compared to the skull simulator and artificial mastoid?

# 2
# Theory

## 2.1 Verification of BCDs

As mentioned earlier, there are different methods to verify the fitting of a BCD. For a percutaneous BCD, an objective measurement using a skull simulator as load is usually performed. The skull simulator simulates the human skull impedance [15]. The verification is performed by attaching the bone anchored hearing device to the abutment of the skull simulator. In response to sound, the bone anchored device vibrates and generates a force output into the skull simulator, which convert these vibrations into an electrical signal. Such force levels (FL) in dB relative (re) to $1\mu N$ representing maximum force output (MFO) of the device and the hearing threshold of the patient, with appropriate vibrational transforms, are used to represent the DR, defined as the difference between hearing thresholds and MFO, of the patient.

There are two different skull simulators that are well established on the market - Verifit (Audioscan, Dorchester, Canada) and SKS 10 (Interacoustics A/S, Middlefart, Denmark), which are based on the same principle as the original TU 1000 developed by B. Håkansson and P. Carlsson (1989). All three skull simulators are shown in figure 2.1. Another artificial load called the Artificial Mastoid type 4930 (Bruel & Kjaer, Denmark) is used for the objective measurement of the mechanical output of passive transcutaneous BCD. It simulates the mechanical characteristics of the human head i.e the mechanical impedance of the human mastoid covered by intact skin, see figure 2.1(d). It has a built-in force transducer that monitors the output force from the BCD and transforms it to an electrical output.

For transcutaneous BCDs, fitting is normally verified in a subjective manner. The verification process is usually performed by recording the vibrations that are transmitted to the skull bone. These vibrations can be recorded in the surrounding tissue or as sound pressure from the outer ear canal or nasal cavity. Reinfeldt et al. (2019) [20], objectively verified the functionality of the BCI through nasal sound pressure, where the implant was tested by electrically stimulating the transducer and measuring the output, that is, nasal sound pressure using a probe microphone in the ipsilateral nostril. There are certain limitations in [20] regarding the completely plugged nostril, and the patients holding their breath during measurements. However, this verification method was a better alternative to all the other verification tools such as Laser-Doppler-vibrometry and reverse transfer function, done during surgery and post-surgery [21]–[23].


**Figure 2.1:** Examples of skull simulator and artificial mastoid. Skull Simulator SKS 10 by Interacoustics [16] (top left); Verifit Skull Simulator by Audioscan [17] (top right); Skull Simulator TU 1000 by B. Håkansson and P. Carlsson (1989) [18] (bottom left); Artificial Mastoid type 4930 by Bruel & Kjaer [19] (bottom right).

Håkansson et al. [9], measured the output force level (OFL) of the BCI transducer coupled to the skull simulator TU 1000 [18] in dB re to $1\mu N$ at 60 and 90 dB SPL re to $20\mu$Pa. The frequency response of the BCI transducer at 60 dB SPL was used to illustrate the audibility of ordinary speech of the BCI transducer. The audibility was verified by plotting the average sound field hearing thresholds of the patients and the MFO of the device along with a spectrum of speech called the long term average speech spectrum (LTASS) from Byrne et al. 1994 [24]. The patient's DR of hearing was in turn determined by subtracting the MFO of the device with the hearing thresholds of patients. The graph from [9], here represented as figure 2.2, illustrates that the LTASS is well above the average hearing thresholds and the noise floor (lowest sound that the device can measure) and below the MFO. The LTASS was extended by following the $30^{th}$ and $99^{th}$ percentiles of speech [25], to form an audibility speech area. Therefore, the average speech was within the DR and considered audible to the average patient except for the higher frequencies.

In a study by Hodgetts et al. (2010) [26], three approaches were compared to estimate the audibility of aided speech using the BAHA. The aided sound-field threshold was investigated for verifying speech audibility of BAHA with two in-situ (refers to when a hearing instrument or other device is being worn) approaches - real ear approach and accelerometer approach. In the real ear approach, the SPL in the ear canal for aided LTASS at 55, 65, and 75 dB SPL speech input was measured by a real ear analyzer and controlled by a reference microphone. Whereas the latter used an accelerometer placed on the backside of the BEST transducer to measure

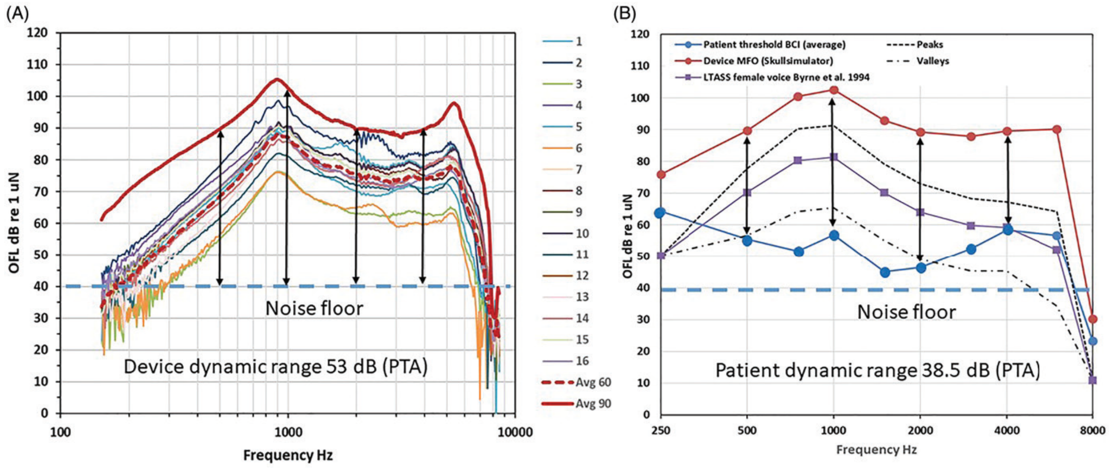


**Figure 2.2:** Indirect estimation of audibility of a BCD on a patient from [9]. (A) Output force levels at 60 dB SPL input (different coloured curves), Maximum force output of the BCI at 90 dB SPL (topmost curve in red), and the maximum dynamic range of the BCI (vertical lines at 0.5, 1, 2 and 4kHz); (B) Average sound field thresholds (blue curve), maximum force output at 90 dB SPL (red curve), LTASS including peak and valley (purple and black curves), and the patient dynamic range (vertical lines at 0.5, 1, 2 and 4kHz)

the acceleration level. These two approaches determined the sensation level (level of aided speech minus threshold in dB) of the LTASS. Consequently, the authors found significant differences between three methods, however, there were certain limitations regarding the measurement of aided response to low level inputs, the low frequency noise floor of the Baha, and the limited frequency resolution of the aided response.

Another study by van Barneveld et al. [27], proposed three methods to determine the fitting ranges of nine different BCDs based on the maximum power output (MPO; highest output level a device can deliver) of the BCD. The first two methods assessed the MPO of BCDs using a skull simulator and the third method using real-ear measurements. Method 1 assessed the input/output behaviour of percutaneous BCDs to warble tone stimuli. On the other hand, for method 2 and 3, the authors calculated the MPO by adding the input level at which the device saturated with the effective gain. The effective gain was calculated by subtracting the patient's aided sound-field thresholds from the audiometric BC thresholds. The authors concluded that all three methods gave comparable results, therefore, if a device cannot be coupled to a skull simulator, one can use the real-ear measurements to assess MPO. Additionally, a "2/3 rule" was suggested to determine the DR of hearing, considering that the DR is equal to 2/3 of the audible range and at least 35 dB wide for a given sensorineural hearing loss component.

A similar study by Mertens et al. [28] determined the maximum output of an active BCI, the Bonebridge (MED-EL company, Innsbruck, Austria), using the Aurical REM system with a probe microphone placed in the occluded contralateral ear canal. In the study input/output measure were obtained and the individual DR were calculated.

In an interesting study by Hodgetts et al. (2018) [29], a novel verification tool was developed for BCDs using a sensitive skin microphone placed on the forehead to capture the vibrations of the skull bone. The skin microphone audibility was determined by capturing its response to pink noise presented at 55, 65, and 75 dB SPL. The study showed equivalent results with percutaneous BCDs verified using the skull simulator, where this approach was not a replacement for skull simulator but an alternative approach for direct measurement of BCDs - percutaneous, active and passive transcutaneous. There are certain limitations in [29] regarding the pink noise used as test signal, the sensitivity of the SM in combination with leakage of sound by-passing the aided bone conduction transmission path.

## 2.2 Pilot study using a skin-drive BCD

In this study, the audibility of a skin-drive BCD was determined and verified in a method similar to [29], but with an earlier version of the skin microphone housed in a brass casing (Hodgetts and Scott, personal communication) which has shown to be less sensitive to leakage of sound. Additional sound isolation was introduced and a more realistic synthetic speech signal instead of pink noise was used, and warble tones for the audibility verification. The skin microphone was used to measure the upper limit of DR of hearing (i.e MPO) and the lower limit defined by hearing thresholds as well as the spectrum of synthesized speech were determined. The audibility verification was performed with the goal that most of the speech spectrum should be within the DR for the user. Similarly, the audibility of the BCD was also determined with a skull simulator and an artificial mastoid, to assess and validate the BCD audibility verification method using the skin microphone.

The speech signal used for the study was the International Speech Test Signal (ISTS). According to [25], the ISTS resembles normal speech but it is not intelligible as it is based on six different languages spoken by female speakers reading the story, "The north wind and the sun", which was cut into small fragments and recomposed in a different order. The ISTS is similar to the LTASS for a female voice as specified by Byrne et al. (1994) [24], [25] and is commonly used to verify the fitting or speech audibility of hearing aids.

# 3
# Methods

This chapter will focus on the study participants, the experimental set-up and the experimental protocol of the study. The limitations that were noticed during the study will be described at the end of this chapter.

## 3.1 Study Participants

Five participants, 2 women and 3 men, who are part of the research group volunteered to be subjects for this pilot study. They are from different age groups (24-67 years) and without any pronounced hearing loss. The subjects gave their informed consent to participate in the study and were seated in the sound-proof room (approximately $16m^3$) at the hearing laboratory at Chalmers University of Technology for the measurements. The study was conducted in accordance with the principles stated in the Declaration of Helsinki.

## 3.2 Experimental Set-up

The experimental set-up for the audibility verification of BCDs using skin microphone is shown in figure 3.1. A detailed description of the sensors and measurement systems used for the experiment are mentioned below.

### 3.2.1 Skin Microphone

As mentioned in the previous chapter, the skin microphone with a plastic housing according to Hodgetts et al. 2018 [29], was initially used for the measurement. Due to its sensitivity towards airborne sound, an earlier prototype skin microphone with brass housing (Hodgetts and Scott, personal communication) was used. The latter includes a preamplifier and a microphone insulated by a foam sealing and a soft ring muff with the microphone inlet open at the center together with an external battery supply (3x1.5 V). Figure 3.2 shows both the skin microphones that were used during the study.

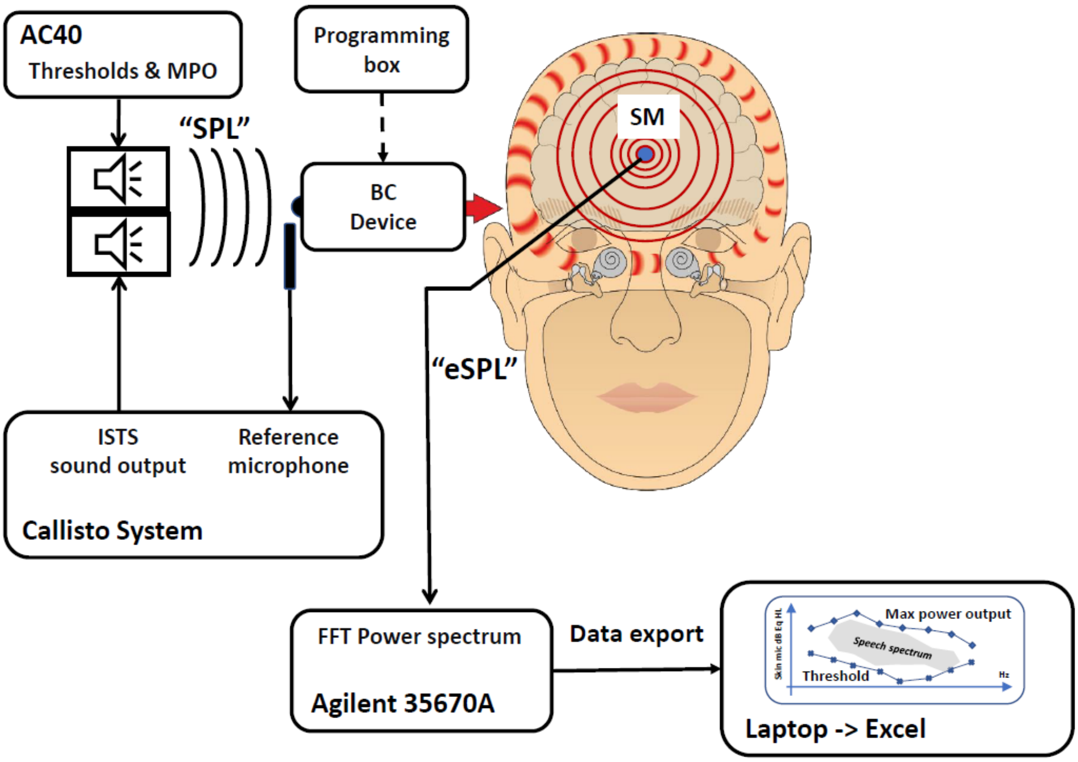


**Figure 3.1:** Experimental set-up for audibility verification of BCDs using skin microphone (SM).

**Figure 3.2:** Skin microphone according to Hodgetts et al. 2018 [29] (left); Previous skin microphone with brass housing (right) according to Hodgetts and Scott (personal communication).

### 3.2.2 Reference BCD

A BAHA, Baha® Intenso (Cochlear BAS, Mölnlycke, Sweden) was used as a reference device. It is a linear bone conduction sound processor with a soft output limiting compressor, and has volume control, gain/filter controls as well as different program settings for various listening situations [30]. It consists of a built-in microphone with a small opening at the front end, a direct audio input, and a plastic snap connector at the back. It works on zinc-air batteries type 675 (1.45 Volts). For this study, Intenso was kept on program 1 which is the general setting suitable for everyday sound environments, and with maximum frequency bandwidth and a volume control setting as high as possible but without the tendency to feedback oscillations. This setting was the same for all subjects in this study; No individual fitting was performed.

### 3.2.3 Callisto Module

Callisto (Interacoustics A/S, Middlefart, Denmark) is a portable diagnostic system that contains REM module and Audiometry module, programmed on Callisto Suite 1.13 software [16]. It consists of two microphones that are for the left and right ear. For this study, only the left microphone was used and connected directly to the skin microphone output. The calibration of reference microphone was done using a 114 dB SPL @ 1 kHz calibrator. The Callisto system was connected to the laptop with a USB cable to provide the ISTS speech signal through the external speaker (Edifier, Beijing, China) and to the reference microphone for SPL control.

### 3.2.4 Agilent 35670A

Agilent 35670A Dynamic Signal Analyzer (Keysight Technologies, Santa Rosa, CA, USA) is a two- or four- channel fast fourier transform (FFT) based spectrum/network analyzer [31]. Its frequency ranges from 122 $\mu$Hz **check micro** to 102.4 kHz with 16-bit analog to digital converter. It was used for the measurement of the FFT power spectrum of the skin microphone output in logarithmic scale in the frequency range 100-12.9k Hz using alternating current coupling, hanning window and 40 root mean square averages to improve the signal to noise ratio.

### 3.2.5 Artificial Mastoid type 4930

Artificial Mastoid Type 4930 by Bruel & Kjaer consists of an inertial mass simulating the mechanical characteristics of the human head that is mounted on a baseplate fixed to a suspension of springs to provide insulation to supportive table or surroundings. The rubberized surface on the artificial mastoid has an adjustable static force arrangement providing 5.4N contact force and it is supposed to work from 50 Hz to 10 kHz under normal conditions [19]. As mentioned earlier, it has a built-in force transducer that is formed by piezoelectric discs and transforms the output force into an electrical output.

The artificial mastoid in this investigation was horizontally placed in the position for the subject's head and fixed to the neck support of the chair, shown in figure 3.3. A soft band was used to attach the Intenso adapter by 4N. The artificial mastoid was connected to a conditional amplifier (Bruel & Kjaer Nexus charge amplifier type 2692-C) to measure the amplified electrical output on Agilent power spectrum.

### 3.2.6 Skull Simulator TU 1000

Håkansson and Carlsson 1989 [18], designed the skull simulator TU 1000; It consists of three masses - coupling, load mass, and accelerometer, that together form the rigid mass insulated by two springs from a heavy frame and silicon cushions. It has a built-in preamplifier for impedance transformation and calibration. Additionally, it consists of two switchable sensitivities called 'ref' and '20 dB'- the precalibrated sensitivity in the 'ref' position of 0.2 V/N and the '20 dB' position for additional gain of 15-25 dB. The skull simulator was placed next to the artificial mastoid i.e in the position for the subject's head and fixed to the neck support of the chair, shown in figure 3.3. Similarly, its electrical output was, in this study, measured as power spectrum by the Agilent system.

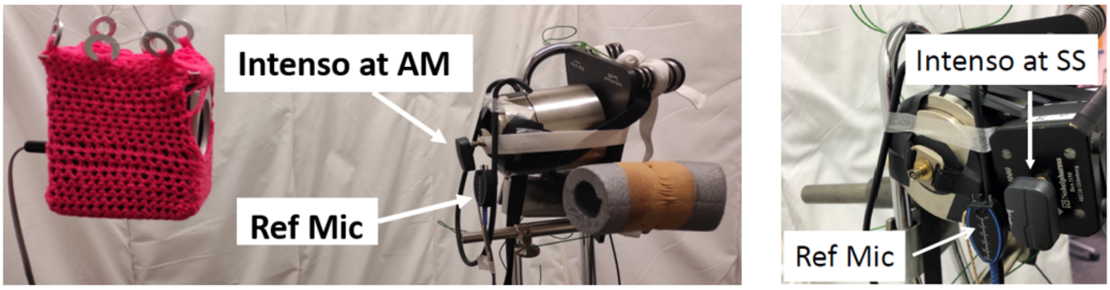


**Figure 3.3:** Experimental set-up on the artificial mastoid (AM) type 4930 and the skull simulator (SS) TU 1000. The same Baha® Intenso and reference microphone were used. The Callisto sound field speaker was wire suspended to the ceiling, carried in a red textile bag and placed approximately 25 cm from the Intenso microphone.

## 3.3 Experimental Protocol

The experimental protocol included an initial audiometry evaluation of both air conduction and bone conduction hearing thresholds of all the five subjects in the sound-proof room. This test was performed by an audiologist, who is also involved in this research study. The audiometry included a warble tone threshold testing from an audiometer AC40 (Interacoustics A/S, Middlefart, Denmark) using earphones (TDH 39) for air-conduction testing and an audiometric transducer (B81) placed on the mastoid for bone-conduction testing. The testing procedure was repeated at audiometric frequencies (250, 500, 750, 1k, 1.5k, 2k, 3k, 4k, 6k, 8k Hz) for each ear, and recorded in dB hearing level (HL) on a graph called an audiogram.

Following the audiometry evaluation, the audibility study was performed on all five subjects. The subjects were asked to insert foam ear-plugs bilaterally (E-A-R Classic Soft) as deep as possible to minimize the occlusion effect [32], see figure 3.4, and breathe calmly during measurements without using a face mask. Then the skin microphone was mounted on the forehead in the middle between the hairline and the eyebrow with the help of a soft-band. The cable from the skin microphone was placed over the subject's head to avoid movement or disturbances on the recorded signal, shown in figure 3.4, and was shielded by an earmuff (Peltor Optime III) for additional sound insulation to avoid picking up sound directly from the speaker. After which, the standard linear BCD, Baha® Intenso, was externally placed on the right mastoid with the help of a soft band, as shown in figure 3.4, and was adjusted to maximum gain and bandwidth, but with the volume control reduced to position 2 on the 3-degree scale to avoid feedback issues. The skin microphone was connected to the Agilent 35670A for the FFT power spectrum analysis. The reference microphone was then placed closed to the BCD to ensure SPL at the hearing aid microphone. The Callisto speaker was 25 cm from the subject in the same plane as the BCD. For the sound field threshold and MPO testing using the BCD in situ warble tones at audiometric frequencies from the AC40 were used.

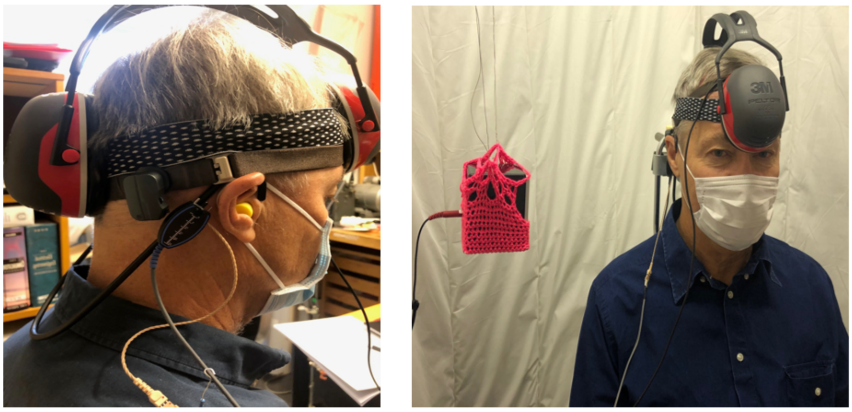

**Figure 3.4:** Real bone measurement in-situ headset with the skin microphone mounted on the forehead and shielded with a earmuff, with Baha® Intenso on a soft band together with the reference microphone placed closed it, and the bilateral deep ear plugs worn by the subject (left); The Callisto sound field speaker placed approximately 25 cm from the subject (right).

The skin microphone response to the sound field warble tones from AC40 and the ISTS speech signal at three sound levels (55, 65, and 75 dB SPL) were measured on Agilent using FFT power spectrum in the frequency range 100- 12.9k Hz. The voltage output from the skin microphone was referred to dB relative to an arbitrarily chosen reference voltage of 10 $\mu V_{rms}$ and presented in a graph named eSPL-o-gram where "e" stands for electrical, referring to the electrical signal from the skin microphone. Initially, the threshold signal measured by the skin microphone was weak and below the microphone's noise floor; An increase of 30 dB above the thresholds resulted in a better signal that could be measured by the skin microphone and then calculated backwards to determine the true threshold. The audibility of a speech signal differs between subjects and the type of BCD used. However, the ISTS speech signal was compared in relative sense to the thresholds and MPO as the skin microphone measured the absolute uncalibrated values.

The raised warble tones was played continuously and the ISTS at 55, 65, and 75 dB SPL were presented for a period of 20 seconds to allow averaging of 40 time samples on Agilent. The measurement of the noise floor of the hearing aid and the skin microphone was performed by turning OFF the speaker. To establish the noise floor of the skin microphone alone, the hearing aid was removed along with the speaker turned OFF. Additionally, leakage of external speech sound at 75 dB SPL directly to the skin microphone without passing through the BCD was measured. These power spectra data were saved on Agilent under different memory files (D1-D6), and were exported as text files through the LabVIEW software. These text files were imported into Microsoft Excel for postprocessing and presentation. The hearing thresholds and MPO were measured by taking the average peak (width of about ±5% of the test frequency) in the spectrum ($V_{rsm}$) using a cursor at each audiometric frequency and then referred to dB re $V_{ref}$= 0.010 $mV_{rms}$. The conversion was done using the formula: $dB = 20 * log_{10}(V_{rms}/V_{ref})$. Similarly, in Excel the wide band power spectrum of ISTS measured in linear $V_{rms}$ was averaged by taking the root mean square around the standard 1/3 octave frequencies (260, 516, 804, 1028, 1604, 1988, 3140, 4004, 6308, 8004), which are close to the audiometric frequencies, and referred to dB re to 0.010 $mV_{rms}$. The time to perform all the measurements on each subject according to the protocol was around 40 minutes.

The OFL of Baha® Intenso at same setting as for the skin microphone was measured using the skull simulator TU 1000 placed in an anechoic chamber [18]. Swept sine at different input levels of 60-, 70-, and 90 dB SPL in the frequency range 100-10k Hz were used. The OFL was represented in dB re to 1$\mu$N, as shown in figure 3.5. At 90 dB SPL, the force level at the resonance frequency (approximately 900 Hz) was around 125 dB re to 1$\mu$N. Considering this to be the maximum value, the MPO using the skin microphone was assessed at 90 dB SPL.

The audibility of a BCD in-situ measured using a skin microphone was compared and verified with the conventional approach i.e. using an artificial mastoid type 4930 (coupler for skin-drive BCD) and a skull simulator TU 1000 (coupler for direct-drive BCD). The TU 1000 was switched to 'ref' position i.e. 0.2 V/N and the artificial mastoid provided a contact force of approximately 4N. Both these devices were placed 25 cm in front of the Callisto sound field speaker, with the Intenso placed at the same head location but attached via a snap coupling to the skull simulator and via a soft band to the artificial mastoid pad. The same reference microphone as used in the RBM in-situ headset was placed closed to the BCD, as shown in figure 3.3. Similar measurement protocol were performed on both these devices. The output signal from the skull simulator and the artificial mastoid measured on Agilent power spectrum were represented in an FL-o-gram that relates to the force at the point of attachment. In Excel, the average $V_{rms}$ value at audiometric frequencies

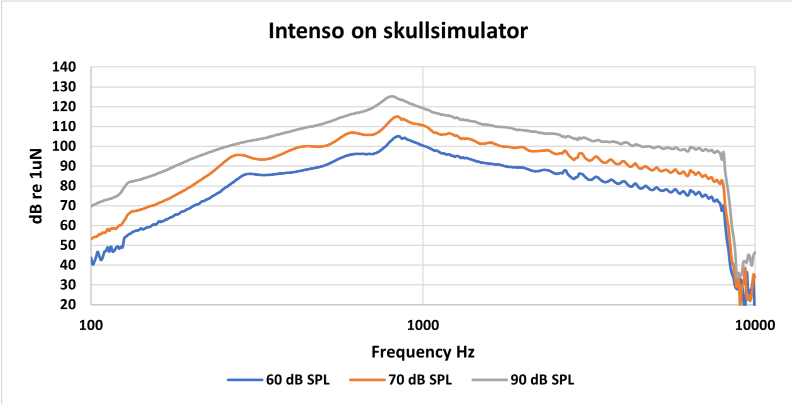


**Figure 3.5:** The output force level of Baha Intenso measured using the skull simulator at different input sound levels - 60, 70, and 90 dB SPL.

were calculated for the warble tones by quadratic averaging around the 1/3 octave frequencies for the ISTS signal, and represented in an FL-o-gram.

The audiometry evaluation and the audibility tests were performed during one session on each subject. The intra-subject variability was investigated via test-retest on one subject without any change in the RBM in-situ headset. Five repeated tests were performed using ISTS 65 dB SPL with 2 minutes pause in between each test. Another five repeated test-retest on the same subject were performed with all the equipment (skin microphone with earmuff, Intenso on soft band, and reference microphone) removed and replaced back to the original set-up to investigate the variability of the method. The subject took a 5 minute break after every measurement. However, only for test-retest the volume of the Intenso was reduced to 1.5 in the 3-degree scale to avoid feedback influence.

## 3.4 Limitations during the study

The skin microphone was tested for sound leakage by transferring a 100 $mV_{rms}$ white noise from Agilent in the frequency range 100-12.9 kHz, through a sound field speaker placed approximately 25 cm in front of the skin microphone. The experimental set-up to test the leakage of sound is shown in figure 3.6. First the skin microphone was placed open faced to measure a reference signal and then mounted on the forehead with a soft band to check for damping. Finally the skin microphone was shielded by an earmuff.

Another test was performed to ensure that the foam earplugs used bilaterally by the subjects minimize direct air conduction hearing. The test included measurement of aided thresholds with earplugs, unaided thresholds with and without earplugs from AC40 at audiometric frequencies for five subjects. The subjects were asked to deeply insert the foam earplugs for the measurement.

As mentioned earlier, MPO is the loudest sound that can be perceived using a BCD

**Figure 3.6:** Skin microphone open faced (left); mounted on the forehead with soft band (middle); mounted on the forehead and with additional shielding by an earmuff (right).

and is an important characteristic while fitting BCDs. The MPO can vary between different BCDs depending on the sound processor and BCD models. van Barneveld et al. [27] investigates the MPO of nine BCDs and found that passive transcutaneous skin-drive BCDs have a lower MPO compared to percutaneous direct-drive BCDs. If the MPO is reached for ordinary speech levels there can be distortion that affect speech perception for a hearing aid user.

The MPO of Baha® Intenso at maximum gain was measured in a similar manner to [28] and method 3 in [27], for warble tones using the AC40 and the skin microphone. With this AC40 setting, the MPO seemed to be very high. At certain frequencies the Intenso also produced feedback noise, perhaps indicating that the device was driven far above its saturation level. However, to verify this, the actual SPL at audiometric frequencies were measured using a sound level meter (Bruel & Kjaer type 2231) in full scale deflection mode and placed at the same plane as the BCD with the same AC40 setting. The sound level meter indicated that the SPL level was in fact around 100 dB re 20 $\mu$Pa.

Another observation was made that the high value of MPO measured using the skin microphone could also be due to direct sound leakage through the skin microphone and/or body-conducted sound for the warble tone stimuli. This was validated by investigating the skin microphone response to sound field warble tones at 90 dB SPL and 80 dB SPL on two subjects who had bilateral earplugs (the same experimental set-up presented in the previous section).

# 4
# Results

This chapter first presents the results of the limitations that were noticed during the study and then the pilot results.

## 4.1 Sound leakage to skin microphone

The sound leakage to the skin microphone was tested on two subjects for the purpose of comparison. The skin microphone response to white noise recorded on Agilent are shown in figure 4.1. The reference signal measured with the open faced skin microphone is represented as the dark blue curve. The orange curve represents the forehead mounted skin microphone with the help of a soft band, which showed very little damping at the lower frequencies. However, more damping of the recorded signal at higher frequencies was observed when compared to the reference signal. This forehead mounted skin microphone shielded with an earmuff resulted in a much better damped signal (gray curve).

With the same set-up, two noise floor measurements were performed, without the input signal. First the subjects were asked to breath calmly (light blue curve) that showed some influence at lower frequencies up to 1-2 kHz. Then the subjects were asked to hold their breath for a few seconds (yellow curve). The difference between the noise floor with and without breathing is very small, hence, calm breathing (without face mask) during the measurements can be acceptable.

With the additional shielding, the gray curve at lower frequencies is attenuated down to the noise floor of the microphone and at high frequencies the curve is just above it. This concludes that the earmuff or similar shielding is essential to avoid leakage of sound during audibility study.


**Figure 4.1:** Skin microphone electrical output to input white noise in dB relative to 0.01 $mV_{rms}$ on Subject 1 and 2.

## 4.2 Earplug attenuation thresholds

Table 4.1 shows the sound field aided and unaided thresholds in dB HL. The attenuation of direct air conduction hearing (unaided with earplugs - unaided without earplugs) using earplugs is 35.3 dB i.e. the four-frequency pure tone average (PTA4 - 500, 1k, 2k, 4k Hz), with a standard deviation (SD) of 2.4 dB. The earplug attenuation in five subjects at audiometric frequencies and its PTA4 are shown in Table 4.2. [33] states that foam earplugs have a noise reduction rating of approximately 30 dB, which explains the above results. Therefore, with the earplugs deeply inserted in the ear canal, we can assume that the sound field warble tone thresholds and MPO at audiometric frequencies as well as wide band spectrum of ISTS is coming through the Intenso device.

**Table 4.1:** Sound field hearing thresholds aided and unaided with earplugs and unaided without earplugs, of five subjects at audiometric frequencies with its four-frequency pure-tone average (PTA4) in dB HL are shown.

| Subject | Condition | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | PTA4 | Hz |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Aided with plugs | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | 17.5 | dB HL |
| | Unaided with plugs | 35 | 45 | 50 | 50 | 35 | 35 | 35 | 45 | 45 | 50 | 43.8 | dB HL |
| | Unaided without plugs | 5 | 10 | 15 | 15 | 10 | 5 | 10 | 5 | 15 | 20 | 8.8 | dB HL |
| 2 | Aided with plugs | 20 | 15 | 15 | 15 | 15 | 15 | 20 | 20 | 35 | 25 | 16.3 | dB HL |
| | Unaided with plugs | 35 | 35 | 35 | 40 | 35 | 40 | 45 | 45 | 55 | 35 | 40.0 | dB HL |
| | Unaided without plugs | 0 | 5 | 5 | 5 | 5 | 5 | 5 | 0 | 5 | 0 | 3.8 | dB HL |
| 3 | Aided with plugs | 20 | 15 | 15 | 15 | 15 | 20 | 25 | 50 | 55 | 50 | 25.0 | dB HL |
| | Unaided with plugs | 40 | 40 | 40 | 35 | 40 | 50 | 65 | 60 | 75 | 65 | 46.3 | dB HL |
| | Unaided without plugs | 0 | 0 | 0 | 5 | 5 | 15 | 20 | 10 | 35 | 35 | 7.5 | dB HL |
| 4 | Aided with plugs | 15 | 15 | 20 | 10 | 15 | 15 | 20 | 25 | 25 | 20 | 16.3 | dB HL |
| | Unaided with plugs | 30 | 30 | 35 | 30 | 35 | 35 | 50 | 50 | 45 | 40 | 36.3 | dB HL |
| | Unaided without plugs | 5 | 5 | 5 | 0 | 5 | 0 | 5 | 0 | 0 | -5 | 1.3 | dB HL |
| 5 | Aided with plugs | 20 | 15 | 10 | 5 | 15 | 15 | 20 | 30 | 35 | 20 | 16.3 | dB HL |
| | Unaided with plugs | 30 | 35 | 35 | 30 | 30 | 35 | 45 | 40 | 45 | 40 | 35.0 | dB HL |
| | Unaided without plugs | 0 | 5 | 5 | 5 | 5 | 5 | 0 | 0 | 5 | 0 | 3.8 | dB HL |

**Table 4.2:** Earplug attenuation in five subjects at audiometric frequencies and its PTA4 in dB.

| Subjects | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | PTA4 | Hz |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 30 | 35 | 35 | 35 | 25 | 30 | 25 | 40 | 30 | 30 | 35.0 | dB |
| 2 | 35 | 30 | 30 | 35 | 30 | 35 | 40 | 45 | 50 | 35 | 36.3 | dB |
| 3 | 40 | 40 | 40 | 30 | 35 | 35 | 45 | 50 | 40 | 30 | 38.8 | dB |
| 4 | 25 | 25 | 30 | 30 | 30 | 35 | 45 | 50 | 45 | 45 | 35.0 | dB |
| 5 | 30 | 30 | 30 | 25 | 25 | 30 | 45 | 40 | 40 | 40 | 31.3 | dB |
| Average | 32 | 32 | 33 | 31 | 29 | 33 | 40 | 45 | 41 | 36 | 35.3 | dB |
| STD | 5.1 | 5.1 | 4.0 | 3.7 | 3.7 | 2.4 | 7.7 | 4.5 | 6.6 | 5.8 | 2.4 | dB |

## 4.3 MPO limited by sound leakage and body-conducted sound to skin microphone

The MPO at 90 dB SPL and 80 dB SPL were investigated with the Intenso turned ON and OFF. It can be noticed from figure 4.2 (a) and (b) that with the device turned ON, the measured curve (straight line in green and yellow) is much higher than curve measured with the device turned OFF (dotted line in green and yellow), which means that body conducted sound and/or direct sound leakage through the skin microphone were not interfering as much with the MPO of the device. It was found that at 80 dB SPL, the attenuation of body conducted sound with the hearing aid turned ON, was higher than 90 dB SPL, on both the subjects. Another reason is that the OFL of Intenso device (figure 3.5) clearly showed that the difference in the OFL for a 10 dB increase (60-70 dB SPL) is the same for a 20 dB increase (70-90 dB SPL) which indicates that the Intenso device had reached its saturation level. Therefore, 80 dB SPL was considered for all MPO measurements during the study. Table 4.3 shows the MPO considered for this study at audiometric frequency together with the respective SPL re to 20 $\mu$Pa that were measured using the sound level meter.

**Table 4.3:** The MPO for warble tone stimuli at audiometric frequency considered for the skin microphone in-situ measurement together with the respective SPL.

| Frequency | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa |

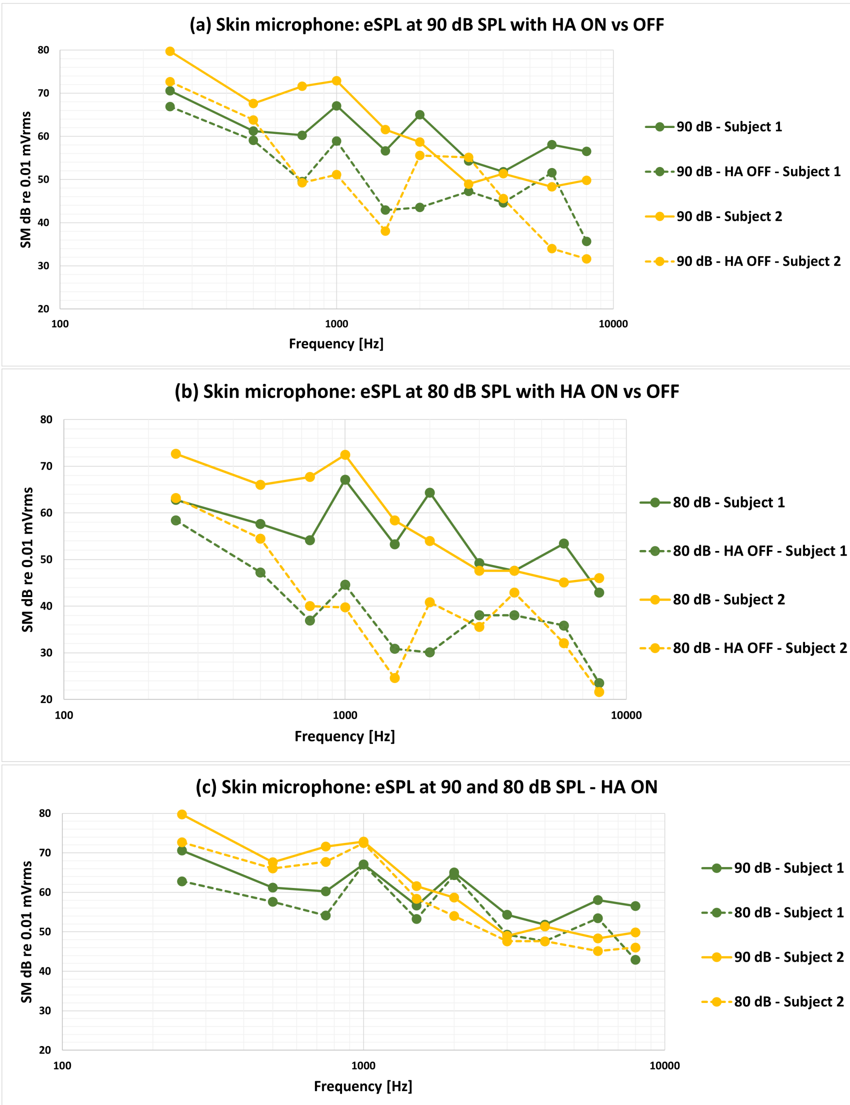


**Figure 4.2:** Skin microphone response to sound field warble tone maximum power output (MPO) at 90 dB SPL (a) and 80 dB SPL (b). The hearing aid was turned ON versus OFF and measured on subjects 1 and 2; (c) Comparison between the skin microphone response to warble tones at 90 dB SPL and 80 dB SPL with the hearing aid turned ON.

## 4.4 Pilot results

Table A.1 from Appendix A presents the AC and BC hearing thresholds of each subject. Their BC PTA4 (500, 1k, 2k, 4k Hz) threshold of the test ear was found to be 5.8 dB (1.3-10 dB) and presented in table A.2 under Appendix A. This explains that the subjects have normal hearing (hearing threshold in the range 0 dB HL to 20 dB HL) except for one subject (No. 3) who has a minor high frequency hearing loss.

The experimental protocol form used for the skin microphone, skull simulator and artificial mastoid measurement method on all the five subjects are shown in Appendix B, C, and D respectively.

### 4.4.1 Skin Microphone: eSPL-o-Gram

The absolute eSPL-o-Gram of each subject (1-5) together with the average are presented in figure 4.3. It represents the skin microphone response to warble tone thresholds and MPO (80 dB SPL) at audiometric frequencies as well as a wide band spectrum of ISTS speech at 55, 65, and 75 dB SPL presented from 200 to 8k Hz. Values outside the frequency range 100-12.9k Hz are almost down to the noise floor and are outside the frequency range of interest. The dynamic range (DR) of hearing calculated from the average eSPL-o-gram at 0.5, 1, 2, and 4 kHz was 57.3, 65.5, 58.5, and 50.7 dB.

The MPO and the ISTS signal were normalized with the patient's own thresholds and referred to dB re threshold. These results are shown in figure 4.4. In the figure 4.5 the average and $\pm 1$ SD calculated in dB values for thresholds, MPO and the ISTS 65 dB SPL are presented. The area between the average 55 and 75 dB SPL (dashed lines) can be represented as a kind of "speech banana" for this ISTS signal. Additionally, the noise floors with and without device on in a quiet environment, and sound leakage at ISTS 75 dB SPL measured from the SM are presented in figure 4.6 for each subject together with the average.

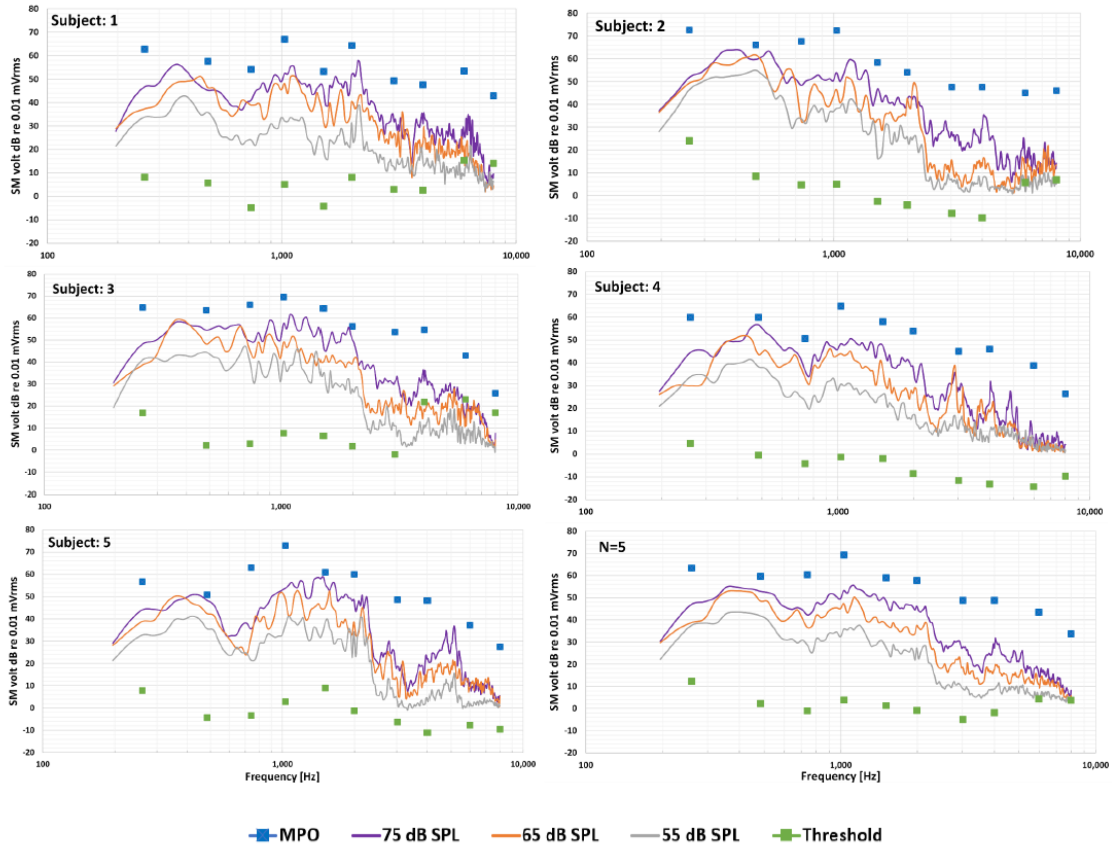


**Figure 4.3:** Absolute eSPL-o-gram obtained with skin microphone (dB re 0.010 mVrms) in each subject (1-5) and as average (N=5). Warble tone thresholds and MPO at audiometric frequencies as well as wide band spectrum of ISTS speech at 55, 65 and 75 dB SPL are shown.

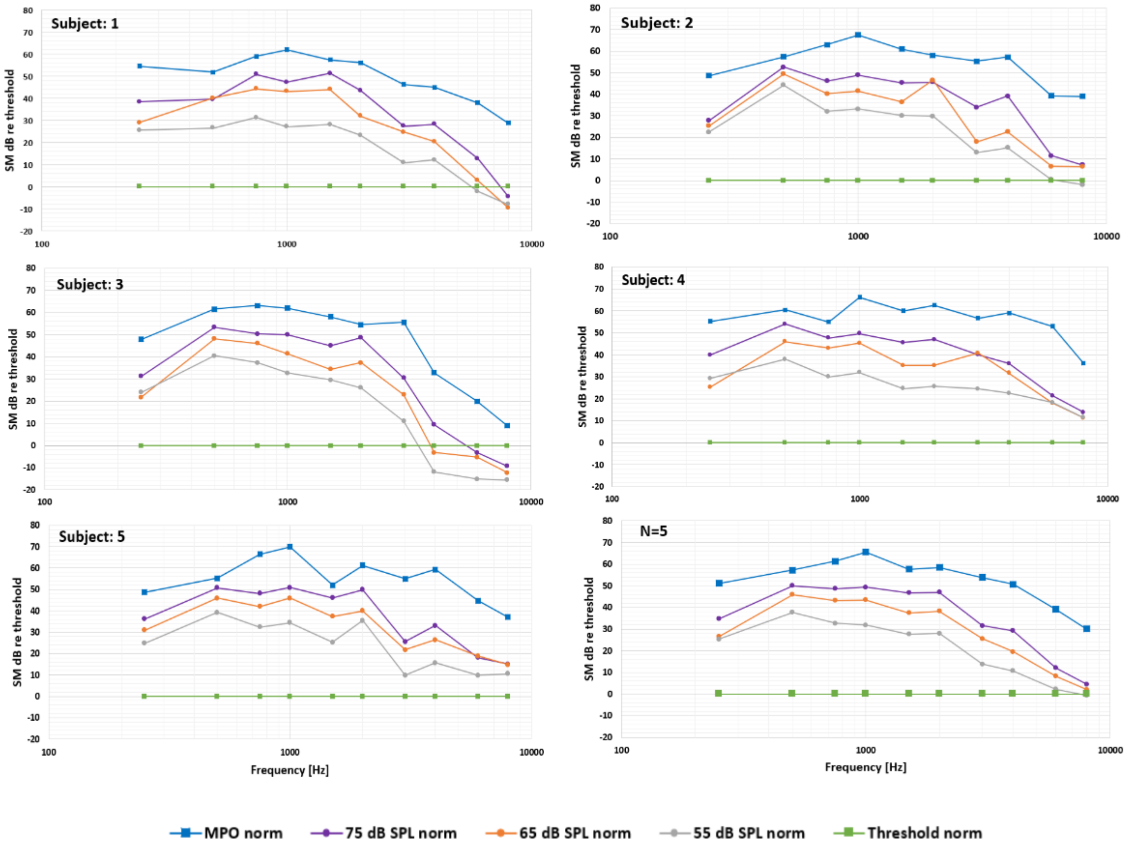


**Figure 4.4:** Normalized eSPL-o-gram: Warble tone MPO and the ISTS speech at 55, 65 and 75 dB SPL normalized by the thresholds (0 dB) at audiometric frequency.

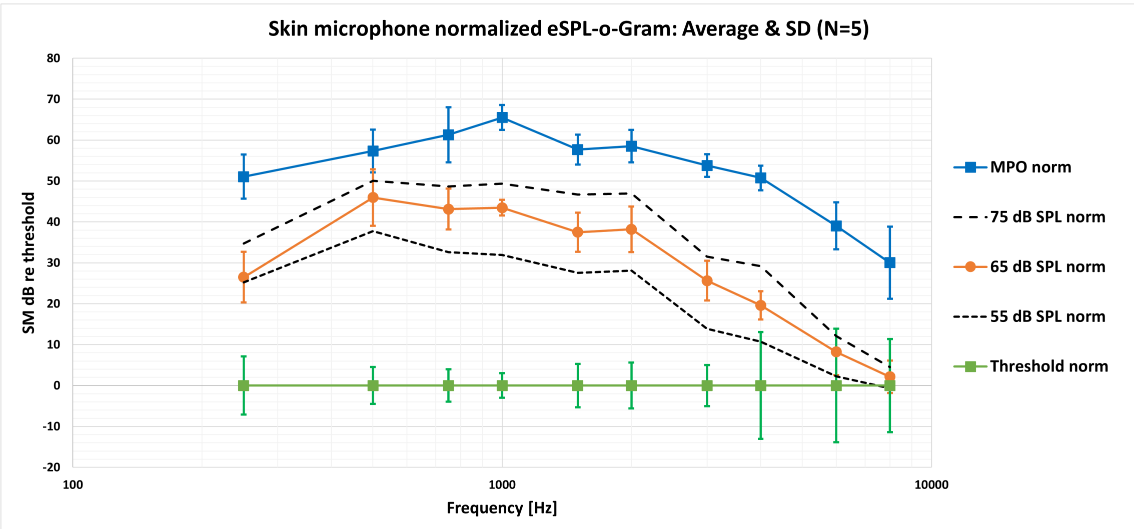


**Figure 4.5:** Normalized eSPL-o-Gram with average and ±1 standard deviation (SD).

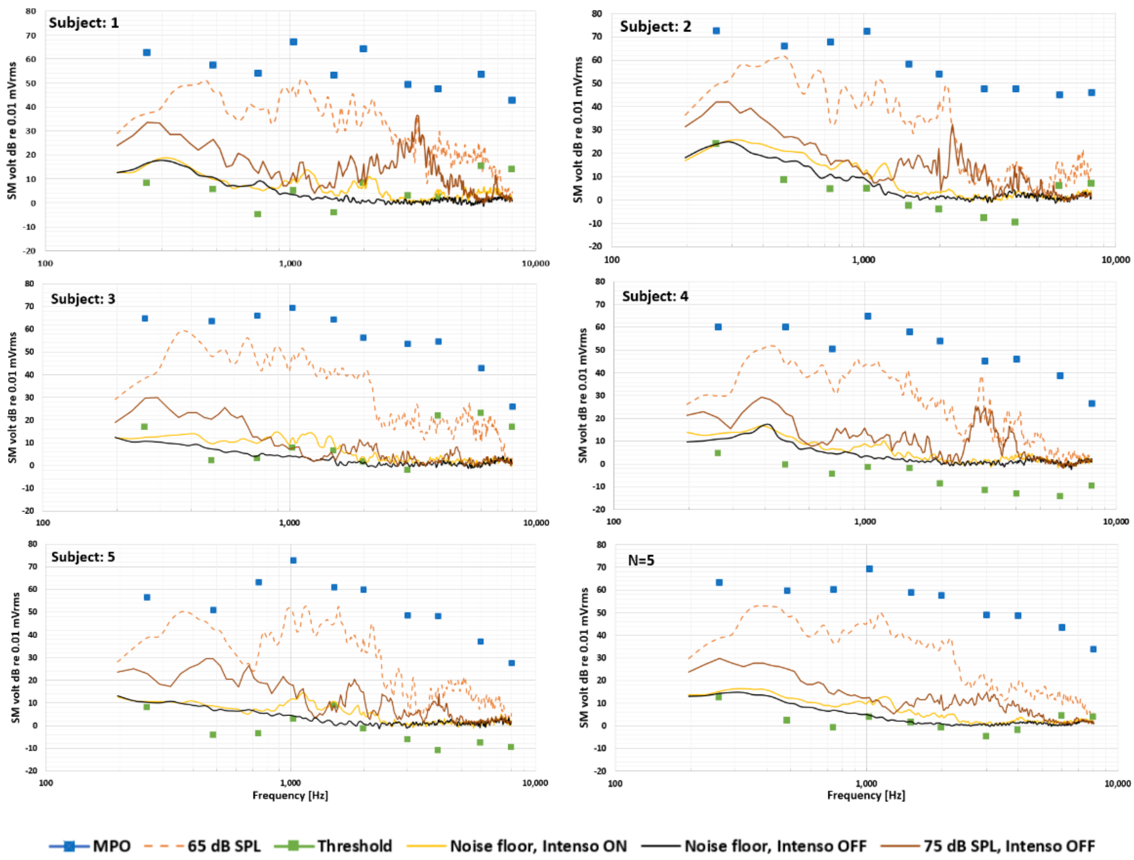


**Figure 4.6:** Limitation of the eSPL-o-gram regarding noise floor and sound leakage by-passing the hearing device in each subject and as average (N=5). Warble tone thresholds and MPO as well as wide band spectrums of ISTS 65 dB SPL with device on, noise floor with and without device ON in quiet environment, and finally sound leakage from ISTS 75 dB SPL without the device ON are shown.

### 4.4.2 Skull simulator: FL-o-Gram

As mentioned earlier, similar experimental set-up and protocol was followed for the measurement on skull simulator. The skull simulator's electrical output to the +30 dB supra thresholds of one subject (No.1) with Intenso attached were determined and referred for the calculation of other subject's supra threshold. This is based on that using a linear BCD like the Intenso, the difference in dB values between subjects from AC40 will change the voltage just as much, for example, the supra threshold for a 10 dB difference results to 3.16 (taking the antilog) times the voltage. This was calculated using the formula: $V2_{rms} = V1_{rms}/10^{((30-T2+T1)/20)}$, where T1 is the subject 1 threshold and T2 is the threshold of other subjects.

The MPO and the ISTS signal will remain the same i.e it will not change between subjects, as their involvement was not required during these measurements. Warble tone thresholds and MPO at audiometric frequencies as well as the wide band spectrum of ISTS at 55, 65, and 75 dB SPL presented for the frequency range 200-

8k Hz are shown in figure 4.7. Similar to the normalization of eSPL-o-Gram shown earlier, the FL-o-Gram obtained with skull simulator was normalized by thresholds (0 dB) that are presented in figure 4.8. Furthermore, the noise floor of the BCD and skull simulator together with the leakage of sound at ISTS 75 dB SPL by-passing the BCD are shown in figure 4.9.

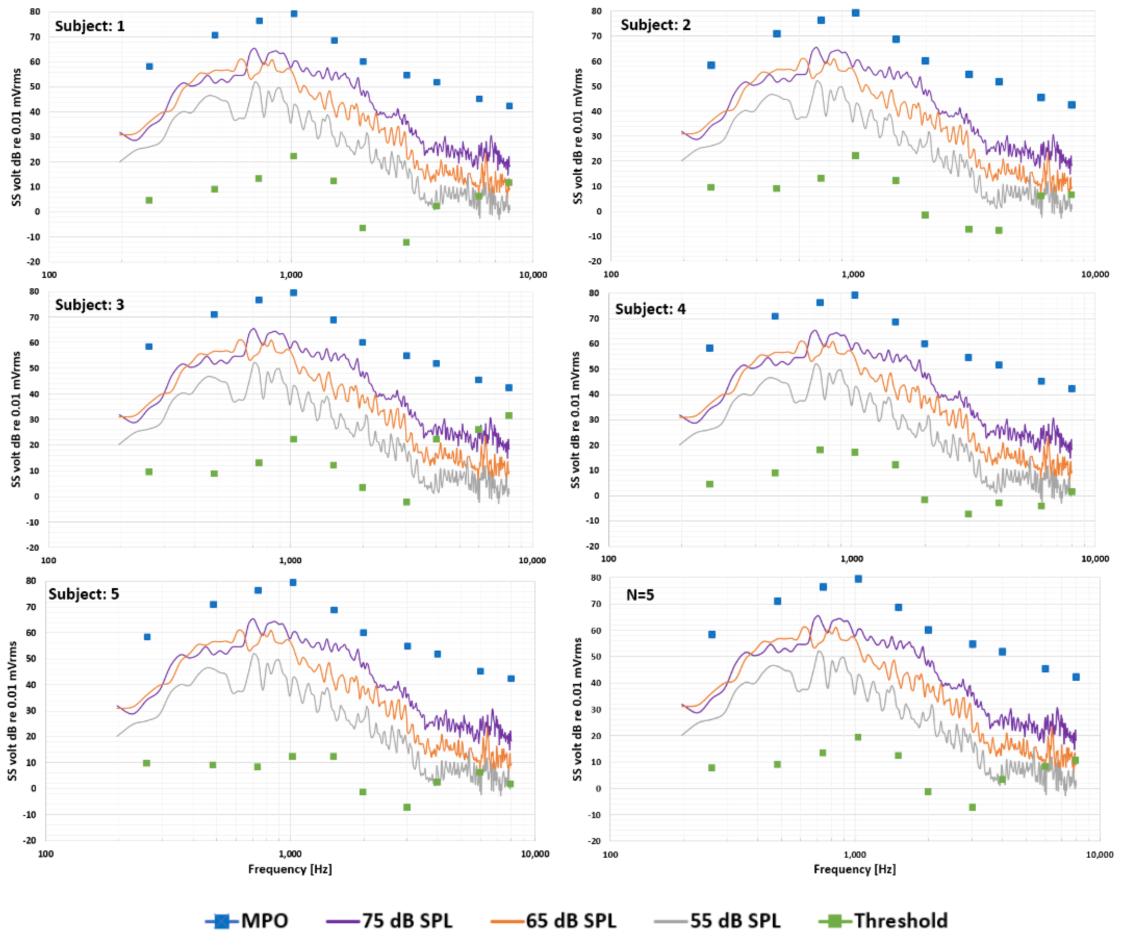


**Figure 4.7:** FL-o-gram obtained with skull simulator (dB re 0.010 mVrms) in each subject (1-5) and as average (N=5). Warble tone thresholds and MPO at audiometric frequencies as well as wide band spectrum of ISTS speech at 55, 65 and 75 dB SPL are shown.

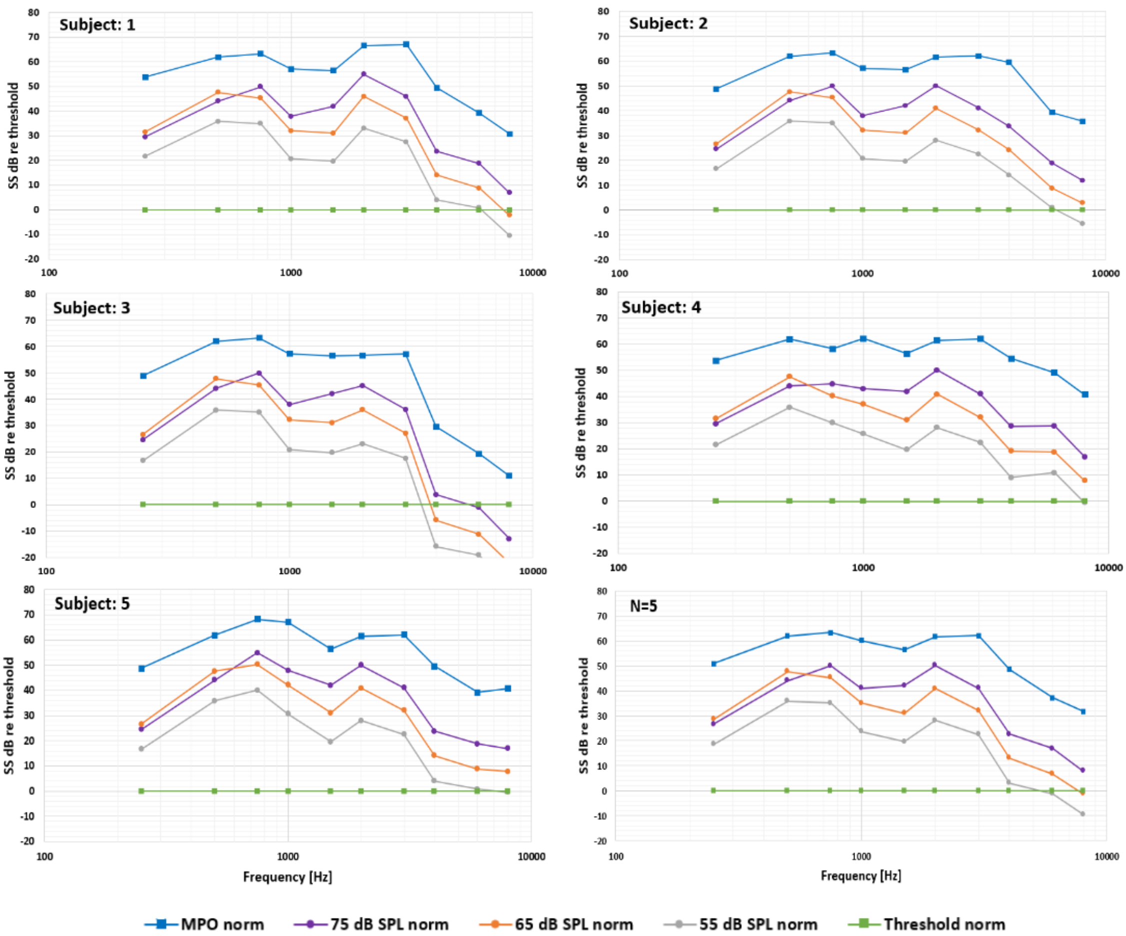


**Figure 4.8:** Normalized FL-o-gram: Warble tone MPO and the ISTS speech at 55, 65 and 75 dB SPL normalized with the thresholds (0 dB) at audiometric frequency are shown.

### 4.4.3 Artificial Mastoid: FL-o-Gram

The experimental set-up with artificial mastoid and the calculation of the aided hearing thresholds for each subject were the same as per the previously mentioned procedure with the skull simulator. The FL-o-Gram obtained with artificial mastoid from each subject and the average are shown in figure 4.10 and the normalized values are shown in figure 4.11. Similarly, the noise floors and sound leakage bypassing the hearing device are presented in figure 4.12.

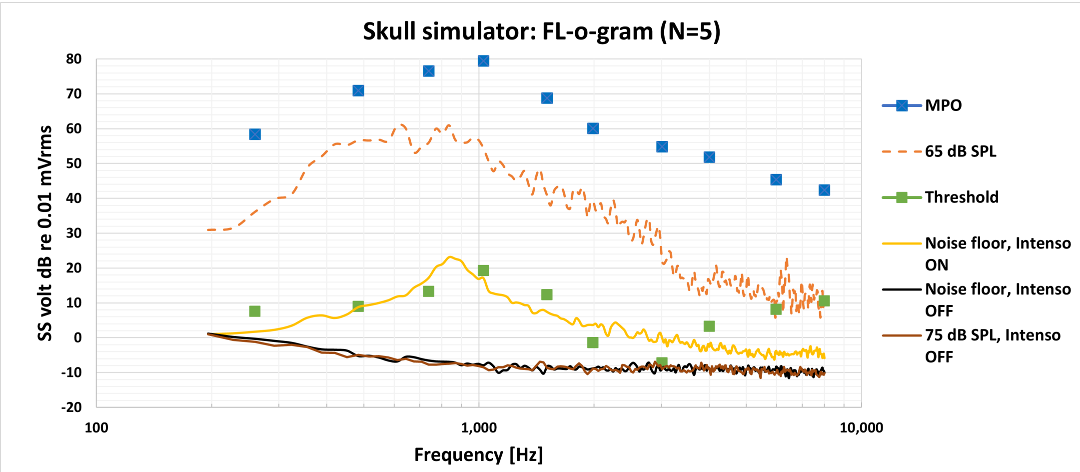


**Figure 4.9:** Limitation of the FL-o-gram regarding noise floor and sound leakage by-passing the hearing device and the skull simulator. Warble tone average thresholds (N=5) and MPO as well as the wide band spectrum of ISTS 65 dB SPL with device ON, noise floor with device ON and OFF (removed) in a quiet environment, and finally sound leakage from ISTS 75 dB SPL with the device OFF are shown.

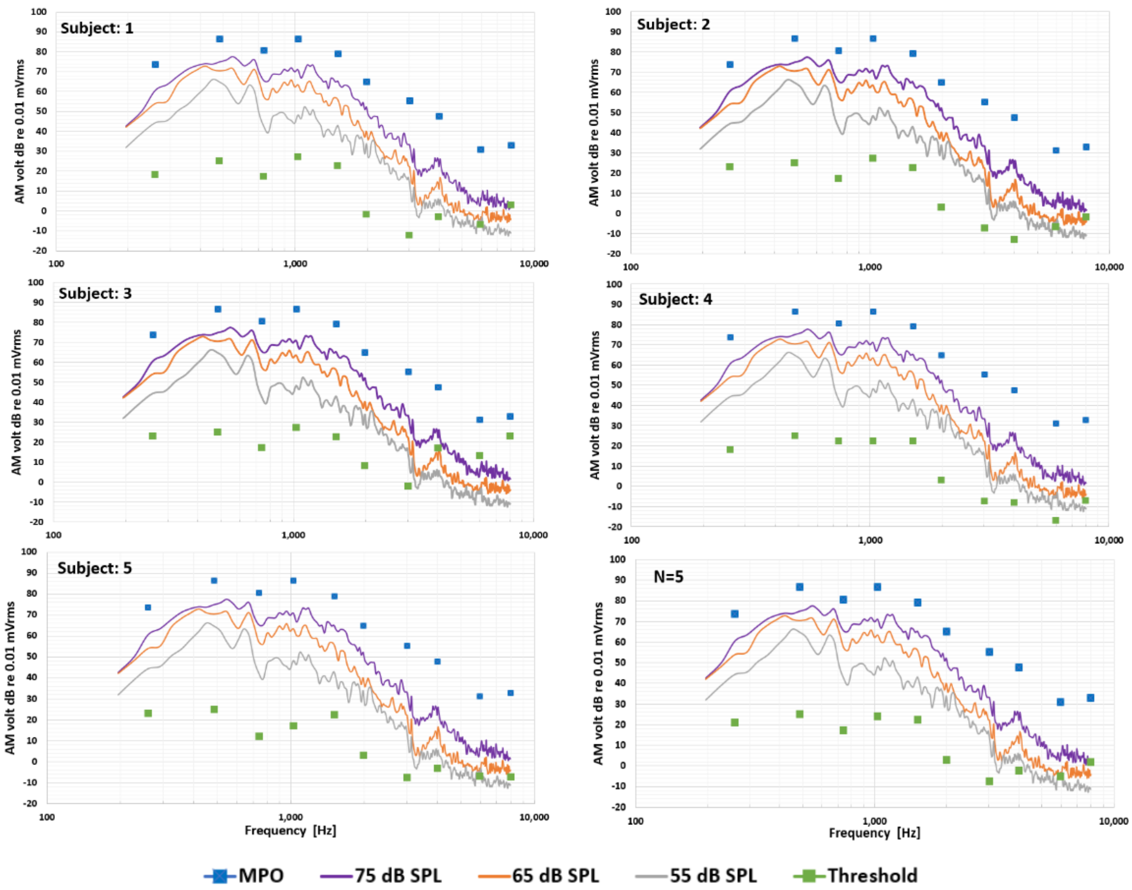


**Figure 4.10:** FL-o-gram obtained with artificial mastoid (dB re 0.010 mVrms) in each subject (1-5) and average (N=5). Warble tone thresholds and MPO at audiometric frequencies as well as wide band spectrum of ISTS speech at 55, 65 and 75 dB SPL are shown.

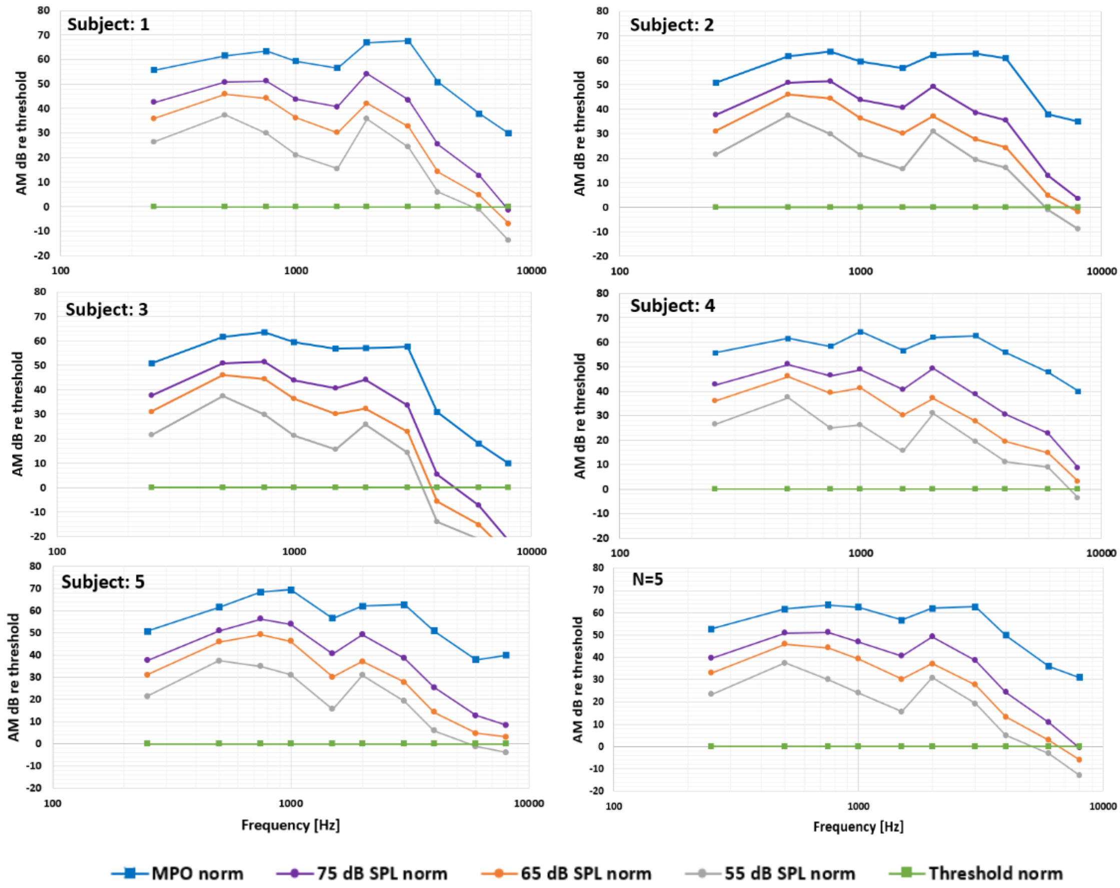


**Figure 4.11:** Normalized FL-o-gram: Warble tone MPO and the ISTS speech at 55, 65 and 75 dB SPL normalized by the thresholds (0 dB) at audiometric frequency are shown.

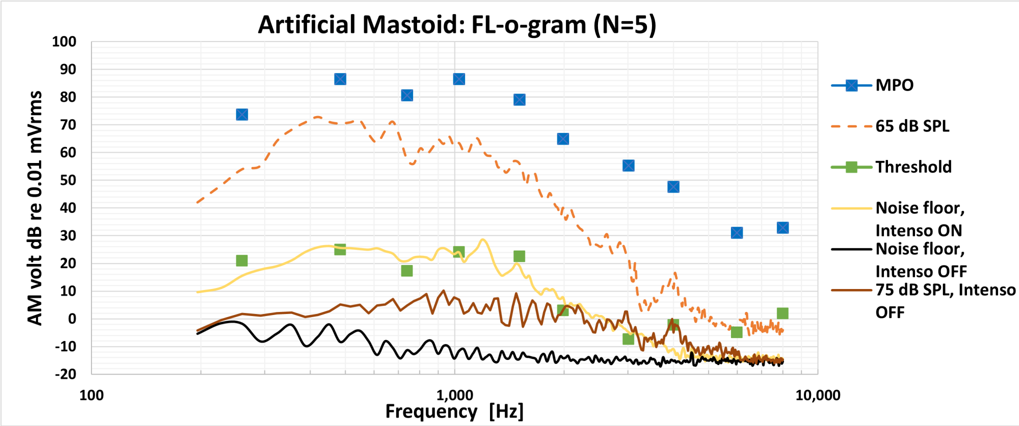


**Figure 4.12:** Limitation of the FL-o-gram regarding noise floor and sound leakage by-passing the hearing device and the artificial mastoid. Warble tone average (N=5) thresholds and MPO as well as the wide band spectrum of ISTS 65 dB SPL with device ON, noise floor with device ON and OFF (removed) in a quiet environment, and finally sound leakage from ISTS 75 dB SPL with the device OFF are shown.

## 4.5 eSPL-o-gram vs FL-o-gram

To verify the eSPL-o-gram obtained from the skin microphone with the FL-o-gram obtained from skull simulator and artificial mastoid, a comparison was made by representing the normalized average (N=5) MPO and ISTS 65 dB SPL in dB re to threshold at audiometric frequencies from all three methods, as shown in figure 4.13.

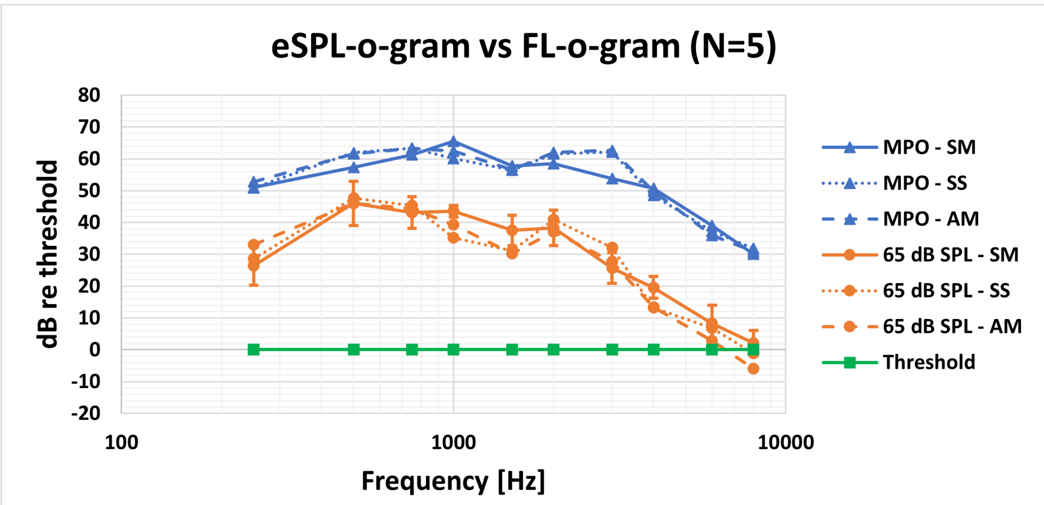


**Figure 4.13:** Normalized eSPL-o-gram using Skin Microphone (SM) versus FL-o-gram using Skull Simulator (SS) and Artificial Mastoid (AM) in dB relative to threshold at audiometric frequencies.

## 4.6 Test-retest Variability

The intra-subject variability with a fixed set-up on one subject (No. 1) repeated five times using the ISTS 65 dB SPL are shown in figure 4.14. The average magnitude and SD were calculated at audiometric frequencies using power averaging. The response of ISTS 65 dB SPL were within the range 30-34 dB and with an average of 32.7 dB in PTA4 and SD 2 dB, in the frequency range 250-8000 Hz. The test-retest variability for the full set-up (includes the removal of equipments after each measurement) on the same subject are shown in figure 4.15. The variability is within the range 28-35 dB in PTA4 and with an average of 31.8 dB and a SD of 3.2 dB.

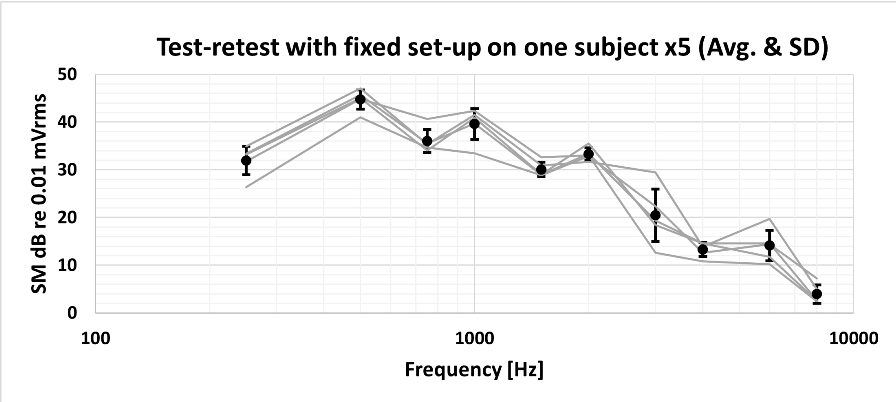


**Figure 4.14:** eSPL-o-gram obtained from five repeated test-retest and the ISTS 65 dB SPL (x5) with shielded skin microphone, Intenso on soft band, and reference microphone fixed on one subject (No. 1). The average and ±1 standard deviation are shown at audiometric frequencies.

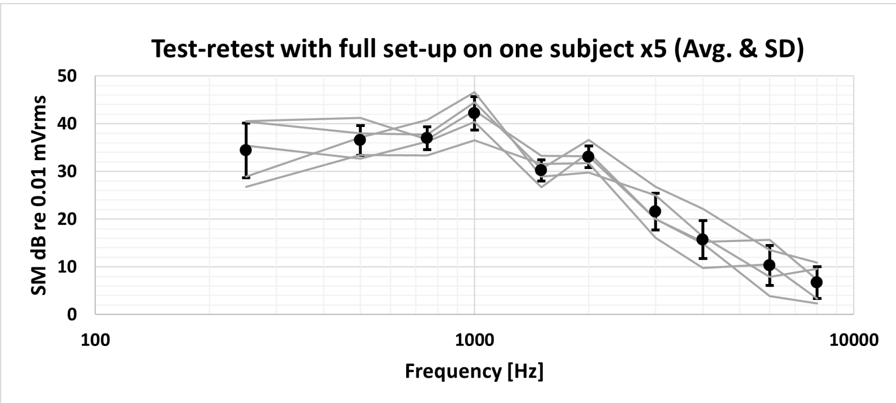


**Figure 4.15:** eSPL-o-gram obtained from five repeated full test-retest and the ISTS 65 dB SPL (x5) measured on one subject (No. 1). The average and ±1 standard deviation are shown at audiometric frequencies.

# 5

# Discussion

## 5.1 RQ1: Elaborate on the validity of using the skin microphone in the REM in-situ system.

This pilot study, based on hearing thresholds, MPO and speech is investigating if a skin microphone can be used for audibility verification of BCDs. The results presented in figure 4.3 show that it is possible to use a skin microphone's output power spectrum for audibility verification in the frequency range 100-12.9k Hz. The power spectrum in $V_{rms}$ is presented as dB re to 0.01 $mV_{rms}$ to get convenient values. Additional sound insulation over the skin microphone was needed to reduce direct sound transmission from the speaker.

From the ISTS RMS spectrum at three sound levels (55-, 65-, and 75 dB SPL) the rms average was calculated from the 1/3 octave bands around the center frequencies (260, 516, 804, 1028, 1604, 1988, 3140, 4004, 6308, 8004) that are close to the audiometric frequencies. To compare the wide band ISTS speech with the narrow band warble tones at threshold and MPO, only the calculated RMS average at audiometric frequencies are considered. According to Rogala and Letowski (2015) [34], earphone hearing thresholds for pure tone, frequency modulated tone and 1/3 octave noise bands can be considered equal for frequencies up to 4000 Hz, which applies for normal hearing listeners as well. They also state that it is commonly assumed that narrow-band signals with a width less than a critical band, like 1/3 octave band noise, produce hearing thresholds similar to pure tones.

The speech signal and MPO were normalized by patient's own hearing thresholds. The reason is that for the audibility of a specific BCD in a given patient, it is not the uncalibrated absolute values from the skin microphone that are of most interest. Instead, it's the relative values, which compare thresholds and MPO with speech levels, that eliminates the need for system calibration and simplifies clinical usage of the method. Therefore, the calibration factors such as sensitivities, windowing effect, FFT and so on, are identical in all measurements and cancel out as the result of the normalization by threshold.

Initially, all levels of ISTS were measured but for the clinical use only the ISTS at 65 dB SPL may be needed, as shown in figure 4.5. It can be observed that most of the speech sounds are on the average audible except at highest frequencies where the sound is close to the thresholds. This is probably due to insufficient transmission of sound by Intenso in a skin-drive system using a soft band and that one of the subjects (No. 3) has a minor high frequency hearing loss (4-8 kHz). With a skin-drive BCD, it can be assumed that poor transmission can occur due to soft band tightness level, i.e the low static pressure on the skin and soft tissues, and that skin attenuates the high frequency vibrations. However, these limitations could be resolved if a direct-drive BCD is used. Therefore, this will be further investigated in the future studies involving real patients with direct-drive devices. Another factor to consider is the speech banana. It can be approximated by taking the $30^{th}$ and $99^{th}$ percentile of the ISTS at 65 dB SPL [24], [25] (not shown in figure 4.5).

Another observation is that throughout the frequency range the true hearing thresholds are almost down to the noise floor except for subject 3 at highest frequencies. However, the ISTS 65 dB SPL and the MPO of the device are well above the noise floor, as shown in figure 4.6. The noise floor at the BCD output originate from ambient sound environment and its microphone noise. This noise floor was heard by the subjects during the measurements. It is common that hearing aids have a noise floor that can be heard if the subjects have normal hearing. Hence, the thresholds were measured at 30 dB supra threshold level and were calculated backward subtracting 30 dB for the true thresholds which apparently can be below the noise floor. Furthermore, it was found that the noise floor in the skin microphone was determined by its internal noise at higher frequencies. At low frequencies, it was the influence from breathing and the leak from the airborne sound that seemed to determine the noise floor. The subject's were asked to breath calmly without their face masks which otherwise increased the breathing sound. Overall, with the Intenso ON, the noise floor is a bit higher than the skin microphone noise especially at mid frequencies, see figure 4.6 for the average eSPL-o-Gram. However, these limitations are much lower than the 65 dB ISTS response for all frequencies so at that level, the method looks to be very robust.

The results from the test-retest presented in figure 4.14, show the intra-subject variability which may originate from subject movements, incidental sounds (e.g., breathing, heartbeat, etc.), ambient environmental sound, and noise from the measuring systems. Moreover, the variability of the full set-up removed and repositioned on the same subject, see figure 4.15, shows that it is slightly more than the former test-retest. This may be related to additional variability from differences in the position of Intenso, skin microphone and earmuff, as well as variability from differences in contact force. However, device position related variability will be cancelled out after normalizing the ISTS 65 dB SPL with the thresholds.

An advantage with the skin microphone placed on the forehead compared to measuring nasal sound pressure [20] is that the patients do not have to hold their breath during the measurement with a plugged nostril. Hodgetts et al. (2010) [26] discovered that the accelerometer approach provided the most accurate characterization of in-situ BAHA performance when compared to the real-ear approach at BAHA microphone. However, this approach is only possible for BEST transducers and on the other hand the skin microphone approach can be used for audibility verification of all types of BCDs. The reason is that the thresholds measured with the skin microphone is not dependent on which device is used and the MPO of the device is related to the threshold. Thus, making the skin microphone approach a viable method that is easy to understand and implement clinically unlike other methods. This novel method will be further investigated on real patients to measure the in-situ audibility and possibly also improve the fitting of their BCDs.

## 5.2 RQ2: Can the sound insulated skin microphone be used as a better or an alternative approach to verify the audibility of BCDs when compared to skull simulator and artificial mastoid?

The skull simulator is a clinically accepted tool for verifying the fitting of direct-drive BCDs, similarly, an artificial mastoid can be used for skin-drive BCDs. The results presented in figure 4.7 for skull simulator and 4.10 for artificial mastoid, clearly shows that speech is perceived at all audiometric frequencies except at highest frequencies where it is close to the noise floor. As mentioned earlier, this can be due the skin-drive BCD coupled to the abutment of the skull simulator and the artificial mastoid pad via the soft band. The skull simulator and artificial mastoid response to warble tone thresholds and MPO at audiometric frequencies and the ISTS at 55, 65, and 75 dB SPL respectively are very similar. Comparing these FL-o-gram results with the eSPL-o-gram, shown in figure 4.13, shows overlapping results. The number of subjects (N=5) used in this study is too small to make statistical analysis but the SD for the skin microphone indicate that these methods are very similar and verifies the accuracy of the eSPL-o-gram method.

The results from figure 4.9 shows that the noise floor of the BCD together with the skull simulator is higher than the noise floor of the skull simulator alone, especially at the mid frequency range. This can be due to the inherent microphone of the BCD and the room's background noise. In general, the skull simulator has a low internal noise. However, the leakage of sound by-passing the brass surface of the skull simulator without Intenso is well below the noise floor, thus it can be negligible. Similarly, figure 4.12 also shows that the noise floor of the artificial mastoid with Intenso is higher in the range 250-3000 Hz compared to the noise floor of the artificial mastoid alone. The reason is that the hearing aids have a noise floor from the microphone that can be heard by subjects with normal hearing and that the artificial mastoid's piezo crystal sensor has a very long noise floor in relation to a microphone (hearing aid or skin microphone). The low-frequency noise of the charge amplifier can also be one of the factors. Moreover, apparently there is more leakage of sound through the exposed rubber surface of the artificial mastoid than through the housing of the skull simulator. Regardless, the ISTS 65 dB SPL speech is well above the noise floor and within the DR of hearing.

The skin microphone approach seems to be an alternative or even better tool in terms of audibility verification of bone conduction hearing aids. Hodgetts et al. 2018 [29], compared their results with only percutaneous BCDs, however, the intention of this novel method is that it should be used for all types of BCDs which will be further investigated on real patients with skin-drive BCDs as well as implantable direct-drive BCDs.

# 6
# Conclusion

The objective measurement of audibility in BCDs in-situ using skin microphone's electrical output is a novel approach, as a tool to improve fitting of such devices. In this study, the audibility of a BAHA on a soft band using skin microphone placed on the forehead was investigated on five study participants with normal hearing. The use of an earmuff or similar additional shielding of the skin microphone is essential to avoid leakage of sound directly to the skin microphone.

The average ISTS at 65 dB SPL for five subjects was found to be audible except for the highest frequencies. The power spectra of speech signal at three different sound levels and MPO of the device normalized with the subject's thresholds provided a simple comparison between eSPL-o-Gram obtained with the skin microphone and the FL-o-Gram obtained with coupler measurements on the skull simulator and the artificial mastoid. The overlapping results from the three methods verified the accuracy of the eSPL-o-gram method. In the future, this method will be further verified on patients with skin-drive and direct-drive BCDs and possibly improve the fitting of their BCDs.

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# A

# Appendix A

The details such as age and gender of the five test subjects in this study are shown in table A.1 together with their AC and BC hearing thresholds across audiometric frequency. Table A.2 is an extended table showing only the BC thresholds from the test ear (right ear) with PTA4 for each subject.

**Table A.1:** Five test subjects of this study, whose age, gender, air-conduction (AC) hearing thresholds and bone-conduction (BC) hearing thresholds of both the ears are shown; R: Right; L: Left

| Subject | Age | Gender | Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 67 | Male | AC R | 0 | 10 | 10 | 10 | 0 | 0 | 5 | 10 | 10 | 20 | dB HL |
| | | | AC L | 0 | 15 | 10 | 15 | 10 | 10 | 10 | 15 | 20 | 25 | dB HL |
| | | | BC R | -5 | 15 | 10 | 5 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL |
| | | | BC L | 0 | 20 | 10 | 10 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL |
| 2 | 24 | Female | AC R | 5 | 5 | 5 | 5 | 5 | 0 | 0 | 0 | 5 | 0 | dB HL |
| | | | AC L | 5 | 10 | 10 | 5 | 5 | 5 | 0 | 0 | 5 | 0 | dB HL |
| | | | BC R | 0 | 15 | 5 | 0 | 10 | 10 | 0 | 5 | 0 | -5 | dB HL |
| | | | BC L | 5 | 15 | 5 | 0 | 5 | 15 | 5 | 5 | -5 | -10 | dB HL |
| 3 | 42 | Female | AC R | 0 | 5 | 5 | 0 | 5 | 10 | 25 | 20 | 35 | 40 | dB HL |
| | | | AC L | 0 | 0 | 5 | 5 | 0 | 15 | 15 | 10 | 35 | 40 | dB HL |
| | | | BC R | -10 | 0 | 5 | 0 | 0 | 5 | 20 | 20 | 20 | 25 | dB HL |
| | | | BC L | -10 | 0 | -5 | 0 | -5 | 5 | 10 | 10 | 20 | 20 | dB HL |
| 4 | 32 | Male | AC R | 0 | 5 | 5 | 5 | 0 | -5 | -5 | -5 | -5 | -5 | dB HL |
| | | | AC L | 0 | 5 | 5 | 0 | 5 | -5 | 5 | 5 | 0 | 0 | dB HL |
| | | | BC R | -5 | 0 | 0 | 5 | 5 | 5 | 5 | 5 | -10 | -10 | dB HL |
| | | | BC L | -5 | 0 | 0 | 0 | 10 | 5 | 10 | 5 | -10 | -10 | dB HL |
| 5 | 53 | Male | AC R | -10 | 5 | 5 | 5 | 5 | 5 | 10 | 10 | 10 | 20 | dB HL |
| | | | AC L | -5 | 0 | 0 | 5 | 5 | 0 | 5 | 5 | 10 | 5 | dB HL |
| | | | BC R | -5 | 10 | 5 | -5 | 0 | -5 | 5 | 5 | 0 | -5 | dB HL |
| | | | BC L | -5 | 10 | 0 | -5 | -5 | 5 | 10 | 0 | 0 | -5 | dB HL |

**Table A.2:** Bone conduction thresholds of five subject on the test ear; R: Right.

| Subject | Test Ear | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | PTA4 | Hz |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | BC R | -5 | 15 | 10 | 5 | 0 | 5 | 10 | 15 | 0 | 5 | 10.0 | dB HL |
| 2 | BC R | 0 | 15 | 5 | 0 | 10 | 10 | 0 | 5 | 0 | -5 | 7.5 | dB HL |
| 3 | BC R | -10 | 0 | 5 | 0 | 0 | 5 | 20 | 20 | 20 | 25 | 6.3 | dB HL |
| 4 | BC R | -5 | 0 | 0 | 5 | 5 | 5 | 5 | 5 | -10 | -10 | 3.8 | dB HL |
| 5 | BC R | -5 | 10 | 5 | -5 | 0 | -5 | 5 | 5 | 0 | -5 | 1.3 | dB HL |

# B
# Appendix B

The protocol form used during the study for the skin microphone in-situ method on five subjects are shown in figure B.1 B.2 B.3 B.4 B.5.

## Subject report form: Audibility study

**Subject ID:** 1 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/1/2021

**Born:** 530705 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

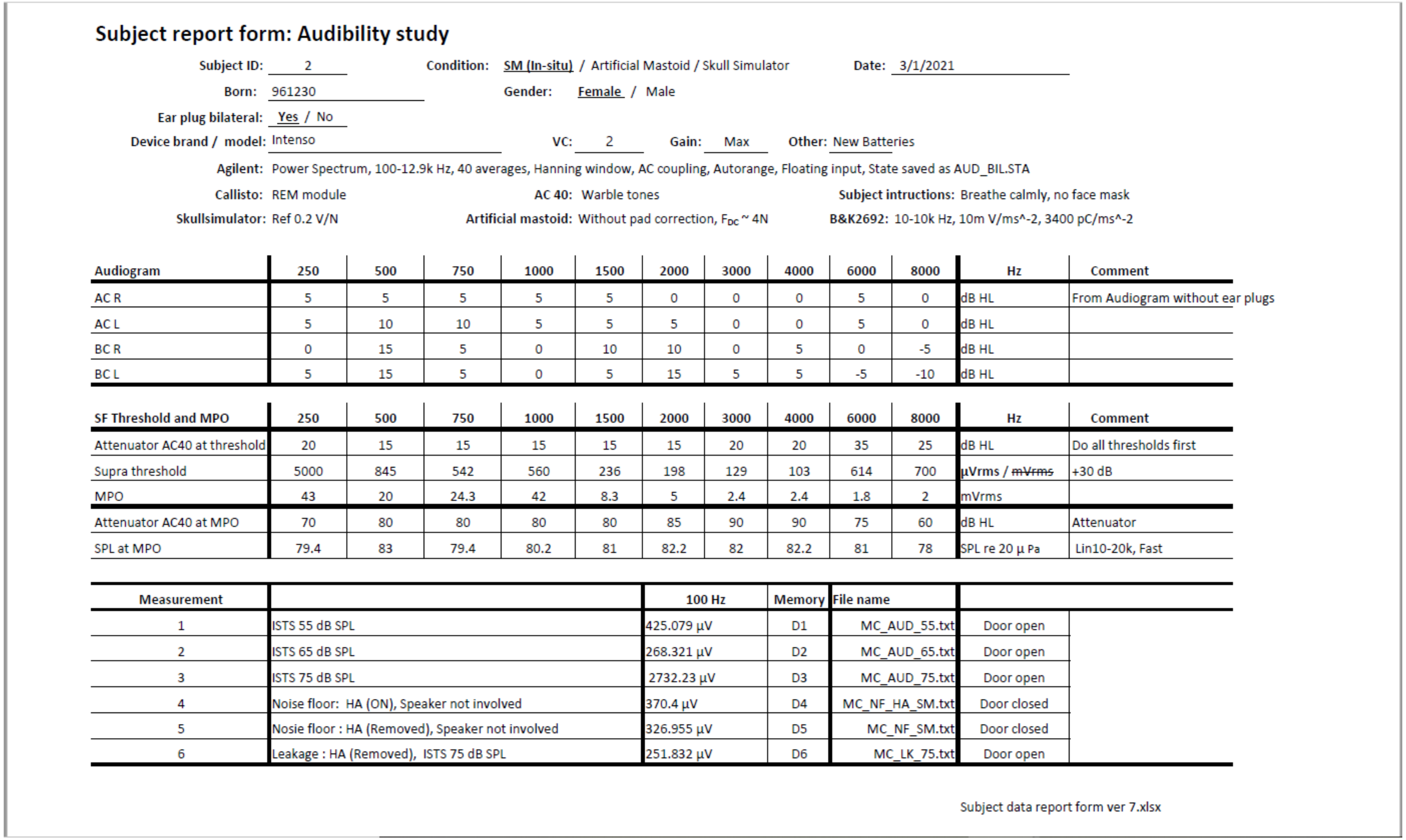
| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 10 | 10 | 10 | 0 | 0 | 5 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 15 | 10 | 15 | 10 | 10 | 10 | 15 | 20 | 25 | dB HL | |
| BC R | -5 | 15 | 10 | 5 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |
| BC L | 0 | 20 | 10 | 10 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Do all thresholds first |
| Supra threshold | 816.7 | 611.4 | 180.5 | 565.9 | 196.5 | 812.3 | 444 | 424.7 | 1860 | 1600 | µVrms / ~~mVrms~~ | +30 dB |
| MPO | 13.8 | 7.6 | 5.1 | 22.6 | 4.6 | 16.5 | 2.9 | 2.4 | 4.7 | 1.4 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | |
|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 156.2 µV | D1 | BH_AUD_55.txt | Door open |
| 2 | ISTS 65 dB SPL | 179.484 µV | D2 | BH_AUD_65.txt | Door open |
| 3 | ISTS 75 dB SPL | 155.917 µV | D3 | BH_AUD_75.txt | Door open |
| 4 | Noise floor: HA (ON), Speaker not involved | 173.804 µV | D4 | BH_NF_HA_SM.txt | Door closed |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 199.07 µV | D5 | BH_NF_SM.txt | Door closed |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 158.7 µV | D6 | BH_LK_75.txt | Door open |

Subject data report form ver 7.xlsx

**Figure B.1:** Subject 1 report form for skin microphone (SM) method



**Subject report form: Audibility study**

Subject ID: 2 Condition: SM (In-situ) / Artificial Mastoid / Skull Simulator Date: 3/1/2021

Born: 961230 Gender: Female / Male

Ear plug bilateral: Yes / No

Device brand / model: Intenso VC: 2 Gain: Max Other: New Batteries

Agilent: Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

Callisto: REM module AC 40: Warble tones Subject intructions: Breathe calmly, no face mask

Skullsimulator: Ref 0.2 V/N Artificial mastoid: Without pad correction, $F_{DC}$ ~ 4N B&K2692: 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 5 | 5 | 5 | 5 | 5 | 0 | 0 | 0 | 5 | 0 | dB HL | From Audiogram without ear plugs |
| AC L | 5 | 10 | 10 | 5 | 5 | 5 | 0 | 0 | 5 | 0 | dB HL | |
| BC R | 0 | 15 | 5 | 0 | 10 | 10 | 0 | 5 | 0 | -5 | dB HL | |
| BC L | 5 | 15 | 5 | 0 | 5 | 15 | 5 | 5 | -5 | -10 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 20 | 15 | 15 | 15 | 15 | 15 | 20 | 20 | 35 | 25 | dB HL | Do all thresholds first |
| Supra threshold | 5000 | 845 | 542 | 560 | 236 | 198 | 129 | 103 | 614 | 700 | µVrms / ~~mVrms~~ | +30 dB |
| MPO | 43 | 20 | 24.3 | 42 | 8.3 | 5 | 2.4 | 2.4 | 1.8 | 2 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | |
|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 425.079 µV | D1 | MC_AUD_55.txt | Door open |
| 2 | ISTS 65 dB SPL | 268.321 µV | D2 | MC_AUD_65.txt | Door open |
| 3 | ISTS 75 dB SPL | 2732.23 µV | D3 | MC_AUD_75.txt | Door open |
| 4 | Noise floor: HA (ON), Speaker not involved | 370.4 µV | D4 | MC_NF_HA_SM.txt | Door closed |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 326.955 µV | D5 | MC_NF_SM.txt | Door closed |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 251.832 µV | D6 | MC_LK_75.txt | Door open |

Subject data report form ver 7.xlsx

**Figure B.2:** Subject 2 report form for skin microphone (SM) method

## Subject report form: Audibility study

**Subject ID:** 3 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/15/2021

**Born:** 780411 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 0 | 5 | 10 | 25 | 20 | 35 | 40 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 0 | 5 | 5 | 0 | 15 | 15 | 10 | 35 | 40 | dB HL | |
| BC R | -10 | 0 | 5 | 0 | 0 | 5 | 20 | 20 | 20 | 25 | dB HL | |
| BC L | -10 | 0 | -5 | 0 | -5 | 5 | 10 | 10 | 20 | 20 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 20 | 15 | 15 | 15 | 15 | 20 | 25 | 50 | 55 | 50 | dB HL | Do all thresholds first |
| Supra threshold | 2206 | 400 | 444 | 763 | 660 | 385 | 253 | 3886 | 141 * | 70 * | µVrms / ~~mVrms~~ | +30 dB; * Threshold at "0 dB" |
| MPO | 17.3 | 15.2 | 20 | 30 | 16.6 | 6.5 | 4.8 | 5.4 | 1.4 | 0.196 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | |
|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 93.1692 µV | D1 | SR_AUD_55.txt | Door open |
| 2 | ISTS 65 dB SPL | 173.449 µV | D2 | SR_AUD_65.txt | Door open |
| 3 | ISTS 75 dB SPL | 135.932 µV | D3 | SR_AUD_75.txt | Door open |
| 4 | Noise floor: HA (ON), Speaker not involved | 113.856 µV | D4 | SR_NF_HA_SM.txt | Door closed |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 133.851 µV | D5 | SR_NF_SM.txt | Door closed |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 159.597 µV | D6 | SR_LK_75.txt | Door open |

Subject data report form ver 7.xlsx

**Figure B.3:** Subject 3 report form for skin microphone (SM) method

**Subject report form: Audibility study**

**Subject ID:** 4 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/15/2021

**Born:** 880418 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| **Audiogram** | **250** | **500** | **750** | **1000** | **1500** | **2000** | **3000** | **4000** | **6000** | **8000** | **Hz** | **Comment** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 5 | 0 | -5 | -5 | -5 | -5 | -5 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 5 | 5 | 0 | 5 | -5 | 5 | 5 | 0 | 0 | dB HL | |
| BC R | -5 | 0 | 0 | 5 | 5 | 5 | 5 | 5 | -10 | -10 | dB HL | |
| BC L | -5 | 0 | 0 | 0 | 10 | 5 | 10 | 5 | -10 | -10 | dB HL | |

| **SF Threshold and MPO** | **250** | **500** | **750** | **1000** | **1500** | **2000** | **3000** | **4000** | **6000** | **8000** | **Hz** | **Comment** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 15 | 15 | 20 | 10 | 15 | 15 | 20 | 25 | 25 | 20 | dB HL | Do all thresholds first |
| Supra threshold | 541 | 301 | 193 | 272 | 251 | 118.5 | 83 | 70 | 61 | 103 | µVrms / ~~mVrms~~ | +30 dB |
| MPO | 10 | 10 | 3.4 | 17.6 | 8 | 5 | 1.8 | 2 | 0.87 | 0.21 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| **Measurement** | | **100 Hz** | **Memory** | **File name** | |
|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 379.264 µV | D1 | KJ_AUD_55.txt | Door open |
| 2 | ISTS 65 dB SPL | 141.456 µV | D2 | KJ_AUD_65.txt | Door open |
| 3 | ISTS 75 dB SPL | 111.895 µV | D3 | KJ_AUD_75.txt | Door open |
| 4 | Noise floor: HA (ON), Speaker not involved | 184.659 µV | D4 | KJ_NF_HA_SM.txt | Door closed |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 196.666 µV | D5 | KJ_NF_SM.txt | Door closed |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 114.724 µV | D6 | KJ_LK_75.txt | Door open |

Subject data report form ver 7.xlsx

**Figure B.4:** Subject 4 report form for skin microphone (SM) method

## Subject report form: Audibility study

**Subject ID:** 5 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/15/2021

**Born:** 670503 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | -10 | 5 | 5 | 5 | 5 | 5 | 10 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | -5 | 0 | 0 | 5 | 5 | 0 | 5 | 5 | 10 | 5 | dB HL | |
| BC R | -5 | 10 | 5 | -5 | 0 | -5 | 5 | 5 | 0 | -5 | dB HL | |
| BC L | -5 | 10 | 0 | -5 | -5 | 5 | 10 | 0 | 0 | -5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 20 | 15 | 10 | 5 | 15 | 15 | 20 | 30 | 35 | 20 | dB HL | Do all thresholds first |
| Supra threshold | 783 | 192 | 214 | 440 | 886 | 272 | 153 | 88 | 131 | 106 | µVrms / ~~mVrms~~ | +30 dB |
| MPO | 6.8 | 3.5 | 14.2 | 44 | 11.2 | 10 | 2.7 | 2.6 | 0.719 | 0.238 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | |
|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 72.9554 µV | D1 | ME_AUD_55.txt | Door open |
| 2 | ISTS 65 dB SPL | 81.7646 µV | D2 | ME_AUD_65.txt | Door open |
| 3 | ISTS 75 dB SPL | 75.3499 µV | D3 | ME_AUD_75.txt | Door open |
| 4 | Noise floor: HA (ON), Speaker not involved | 69.3337 µV | D4 | ME_NF_HA_SM.txt | Door closed |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 99.2499 µV | D5 | ME_NF_SM.txt | Door closed |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 86.9356 µV | D6 | ME_LK_75.txt | Door open |

Subject data report form ver 7.xlsx

**Figure B.5:** Subject 5 report form for skin microphone (SM) method

# C
# Appendix C

The protocol form used during the study for the artificial mastoid method on five subjects are shown in figure C.1 C.2 C.3 C.4 C.5.

**Subject report form: Audibility study**

**Subject ID:** 1 **Condition:** SM (In-situ) / <u>Artificial Mastoid</u> / Skull Simulator **Date:** 3/23/2021

**Born:** 530705 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 10 | 10 | 10 | 0 | 0 | 5 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 15 | 10 | 15 | 10 | 10 | 10 | 15 | 20 | 25 | dB HL | |
| BC R | -5 | 15 | 10 | 5 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |
| BC L | 0 | 20 | 10 | 10 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Do all thresholds first, measured 03/01/2021 |
| Supra threshold | 2.5 | 5.6 | 2.3 | 7.2 | 4.2 | 0.25 | 0.076 | 0.218 | 0.143 | 0.44 | ~~µVrms~~ / mVrms | +30 dB |
| MPO | 48.6 | 212.6 | 107.3 | 212.7 | 90.1 | 17.7 | 5.8 | 2.4 | 0.356 | 0.44 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 13.8117 µV | D1 | AM_AUD_55.txt | Door open | |
| 2 | ISTS 65 dB SPL | 28.834 µV | D2 | AM_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 60.7906 µV | D3 | AM_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 10.6606 µV | D4 | AM_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 8.55871 µV | D5 | AM_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 8.23121 µV | D6 | AM_LK_75.txt | Door open | |

Subject data report form ver 7.xlsx

**Figure C.1:** Subject 1 report form for artificial mastoid method

**Subject report form: Audibility study**

**Subject ID:** 2 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/23/2021

**Born:** 961230 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 5 | 5 | 5 | 5 | 5 | 0 | 0 | 0 | 5 | 0 | dB HL | From Audiogram without ear plugs |
| AC L | 5 | 10 | 10 | 5 | 5 | 5 | 0 | 0 | 5 | 0 | dB HL | |
| BC R | 0 | 15 | 5 | 0 | 10 | 10 | 0 | 5 | 0 | -5 | dB HL | |
| BC L | 5 | 15 | 5 | 0 | 5 | 15 | 5 | 5 | -5 | -10 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 2 threshold AC40 | 20 | 15 | 15 | 15 | 15 | 15 | 20 | 20 | 35 | 25 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 1 Supra threshold | 2.5 | 5.6 | 2.3 | 7.2 | 4.2 | 0.25 | 0.076 | 0.218 | 0.143 | 0.44 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/23/2021 |
| Subject 2 Supra threshold | 0.141 | 0.177 | 0.073 | 0.228 | 0.133 | 0.014 | 0.004 | 0.002 | 0.005 | 0.008 | ~~µVrms~~ / mVrms | +30 dB , Subject 2 supra threshold based on Subject 1 supra threshold |
| MPO | 48.6 | 212.6 | 107.3 | 212.7 | 90.1 | 17.7 | 5.8 | 2.4 | 0.356 | 0.44 | mVrms | Measured on 03/23/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 13.8117 µV | D1 | AM_AUD_55.txt | Door open | Measured on 03/23/2021 |
| 2 | ISTS 65 dB SPL | 28.834 µV | D2 | AM_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 60.7906 µV | D3 | AM_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 10.6606 µV | D4 | AM_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 8.55871 µV | D5 | AM_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 8.23121 µV | D6 | AM_LK_75.txt | Door open | |

Subject data report form ver 7.xlsx

**Figure C.2:** Subject 2 report form for artificial mastoid method

**Subject report form: Audibility study**

**Subject ID:** 3 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/23/2021

**Born:** 780411 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 0 | 5 | 10 | 25 | 20 | 35 | 40 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 0 | 5 | 5 | 0 | 15 | 15 | 10 | 35 | 40 | dB HL | |
| BC R | -10 | 0 | 5 | 0 | 0 | 5 | 20 | 20 | 20 | 25 | dB HL | |
| BC L | -10 | 0 | -5 | 0 | -5 | 5 | 10 | 10 | 20 | 20 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 3 threshold AC40 | 20 | 15 | 15 | 15 | 15 | 20 | 25 | 50 | 55 | 50 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 2.5 | 5.6 | 2.3 | 7.2 | 4.2 | 0.25 | 0.076 | 0.218 | 0.143 | 0.44 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/23/2021 |
| Subject 3 Supra threshold | 0.141 | 0.177 | 0.073 | 0.228 | 0.133 | 0.025 | 0.008 | 0.069 | 0.045 | 0.139 | ~~µVrms~~ / mVrms | +30 dB , Subject 3 supra threshold based on subject 1 supra threshold |
| MPO | 48.6 | 212.6 | 107.3 | 212.7 | 90.1 | 17.7 | 5.8 | 2.4 | 0.356 | 0.44 | mVrms | Measured on 03/23/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 13.8117 µV | D1 | AM_AUD_55.txt | Door open | Measured on 03/23/2021 |
| 2 | ISTS 65 dB SPL | 28.834 µV | D2 | AM_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 60.7906 µV | D3 | AM_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 10.6606 µV | D4 | AM_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 8.55871 µV | D5 | AM_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 8.23121 µV | D6 | AM_LK_75.txt | Door open | |

Subject data report form ver 7.xlsx

**Figure C.3:** Subject 3 report form for artificial mastoid method

## Subject report form: Audibility study

**Subject ID:** 4 **Condition:** SM (In-situ) / <u>Artificial Mastoid</u> / Skull Simulator **Date:** 3/23/2021

**Born:** 880418 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 5 | 0 | -5 | -5 | -5 | -5 | -5 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 5 | 5 | 0 | 5 | -5 | 5 | 5 | 0 | 0 | dB HL | |
| BC R | -5 | 0 | 0 | 5 | 5 | 5 | 5 | 5 | -10 | -10 | dB HL | |
| BC L | -5 | 0 | 0 | 0 | 10 | 5 | 10 | 5 | -10 | -10 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 4 threshold AC40 | 15 | 15 | 20 | 10 | 15 | 15 | 20 | 25 | 25 | 20 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 2.5 | 5.6 | 2.3 | 7.2 | 4.2 | 0.25 | 0.076 | 0.218 | 0.143 | 0.44 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/23/2021 |
| Subject 4 Supra threshold | 0.079 | 0.177 | 0.129 | 0.128 | 0.133 | 0.014 | 0.004 | 0.004 | 0.001 | 0.004 | ~~µVrms~~ / mVrms | +30 dB , Subject 4 supra threshold based on subject 1 supra threshold |
| MPO | 48.6 | 212.6 | 107.3 | 212.7 | 90.1 | 17.7 | 5.8 | 2.4 | 0.356 | 0.44 | mVrms | Measured on 03/23/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 13.8117 µV | D1 | AM_AUD_55.txt | Door open | Measured on 03/23/2021 |
| 2 | ISTS 65 dB SPL | 28.834 µV | D2 | AM_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 60.7906 µV | D3 | AM_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 10.6606 µV | D4 | AM_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 8.55871 µV | D5 | AM_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 8.23121 µV | D6 | AM_LK_75.txt | Door open | |

Subject data report form ver 6.xlsx

**Figure C.4:** Subject 4 report form for artificial mastoid method

**Subject report form: Audibility study**

**Subject ID:** 5 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/23/2021

**Born:** 670503 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | -10 | 5 | 5 | 5 | 5 | 5 | 10 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | -5 | 0 | 0 | 5 | 5 | 0 | 5 | 5 | 10 | 5 | dB HL | |
| BC R | -5 | 10 | 5 | -5 | 0 | -5 | 5 | 5 | 0 | -5 | dB HL | |
| BC L | -5 | 10 | 0 | -5 | -5 | 5 | 10 | 0 | 0 | -5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 5 threshold AC40 | 20 | 15 | 10 | 5 | 15 | 15 | 20 | 30 | 35 | 20 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 2.5 | 5.6 | 2.3 | 7.2 | 4.2 | 0.25 | 0.076 | 0.218 | 0.143 | 0.44 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/23/2021 |
| Subject 5 Supra threshold | 0.141 | 0.177 | 0.041 | 0.072 | 0.133 | 0.014 | 0.004 | 0.007 | 0.005 | 0.004 | ~~µVrms~~ / mVrms | +30 dB , Subject 5 supra threshold based on subject 1 supra threshold |
| MPO | 48.6 | 212.6 | 107.3 | 212.7 | 90.1 | 17.7 | 5.8 | 2.4 | 0.356 | 0.44 | mVrms | Measured on 03/23/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 13.8117 µV | D1 | AM_AUD_55.txt | Door open | Measured on 03/23/2021 |
| 2 | ISTS 65 dB SPL | 28.834 µV | D2 | AM_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 60.7906 µV | D3 | AM_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 10.6606 µV | D4 | AM_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 8.55871 µV | D5 | AM_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 8.23121 µV | D6 | AM_LK_75.txt | Door open | |

Subject data report form ver 7.xlsx

**Figure C.5:** Subject 5 report form for artificial mastoid method

# D

# Appendix D

The protocol form used during the study for the skull simulator method on five subjects are shown in figure D.1 D.2 D.3 D.4 D.5.

## Subject report form: Audibility study

**Subject ID:** 1 **Condition:** SM (In-situ) / Artificial Mastoid / <u>Skull Simulator</u> **Date:** 3/5/2021

**Born:** 530705 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:** New Batteries

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

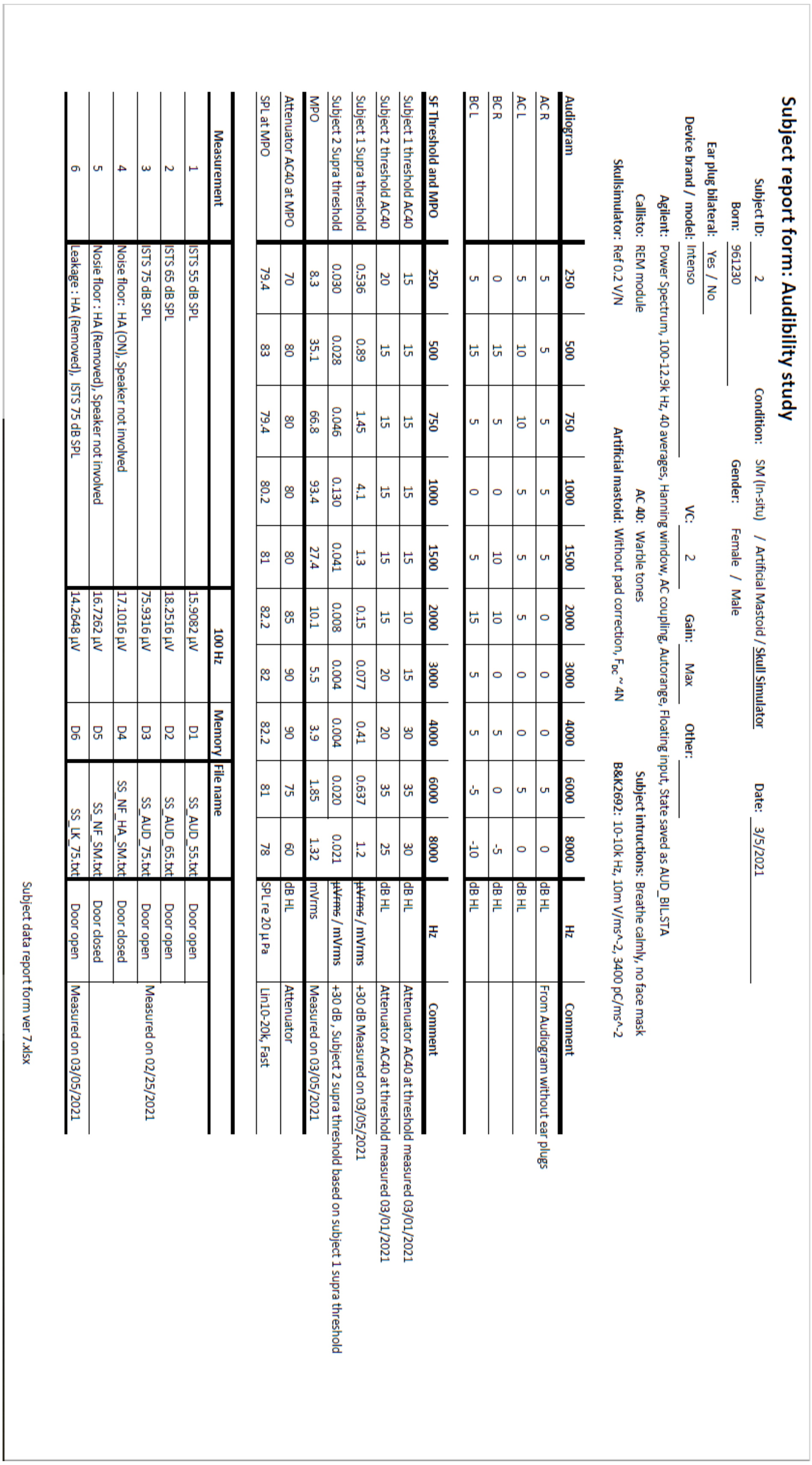
| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 10 | 10 | 10 | 0 | 0 | 5 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 15 | 10 | 15 | 10 | 10 | 10 | 15 | 20 | 25 | dB HL | |
| BC R | -5 | 15 | 10 | 5 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |
| BC L | 0 | 20 | 10 | 10 | 0 | 5 | 10 | 15 | 0 | 5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Attenuator AC40 at threshold | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Do all thresholds first, measured 03/01/2021 |
| Supra threshold | 0.536 | 0.89 | 1.45 | 4.1 | 1.3 | 0.15 | 0.077 | 0.41 | 0.637 | 1.2 | ~~µVrms~~ / mVrms | +30 dB |
| MPO | 8.3 | 35.1 | 66.8 | 93.4 | 27.4 | 10.1 | 5.5 | 3.9 | 1.85 | 1.32 | mVrms | |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 15.9082 µV | D1 | SS_AUD_55.txt | Door open | Measured on 02/25/2021 |
| 2 | ISTS 65 dB SPL | 18.2516 µV | D2 | SS_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 75.9316 µV | D3 | SS_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 17.1016 µV | D4 | SS_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 16.7262 µV | D5 | SS_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 14.2648 µV | D6 | SS_LK_75.txt | Door open | Measured on 03/05/2021 |

Subject data report form ver 7.xlsx

**Figure D.1:** Subject 1 report form for skull simulator method



**Subject report form: Audibility study**

Subject ID: 2 Condition: SM (In-situ) / Artificial Mastoid / **Skull Simulator** Date: 3/5/2021

Born: 961230 Gender: Female / Male

Ear plug bilateral: Yes / No

Device brand / model: Intenso VC: 2 Gain: Max Other:

Agilent: Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

Callisto: REM module AC 40: Warble tones Subject intructions: Breathe calmly, no face mask

Skullsimulator: Ref 0.2 V/N Artificial mastoid: Without pad correction, $F_{DC}$ ~ 4N B&K2692: 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 5 | 5 | 5 | 5 | 5 | 0 | 0 | 0 | 5 | 0 | dB HL | From Audiogram without ear plugs |
| AC L | 5 | 10 | 10 | 5 | 5 | 5 | 0 | 0 | 5 | 0 | dB HL | |
| BC R | 0 | 15 | 5 | 0 | 10 | 10 | 0 | 5 | 0 | -5 | dB HL | |
| BC L | 5 | 15 | 5 | 0 | 5 | 15 | 5 | 5 | -5 | -10 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 2 threshold AC40 | 20 | 15 | 15 | 15 | 15 | 15 | 20 | 20 | 35 | 25 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 1 Supra threshold | 0.536 | 0.89 | 1.45 | 4.1 | 1.3 | 0.15 | 0.077 | 0.41 | 0.637 | 1.2 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/05/2021 |
| Subject 2 Supra threshold | 0.030 | 0.028 | 0.046 | 0.130 | 0.041 | 0.008 | 0.004 | 0.004 | 0.020 | 0.021 | ~~µVrms~~ / mVrms | +30 dB , Subject 2 supra threshold based on subject 1 supra threshold |
| MPO | 8.3 | 35.1 | 66.8 | 93.4 | 27.4 | 10.1 | 5.5 | 3.9 | 1.85 | 1.32 | mVrms | Measured on 03/05/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 15.9082 µV | D1 | SS_AUD_55.txt | Door open | Measured on 02/25/2021 |
| 2 | ISTS 65 dB SPL | 18.2516 µV | D2 | SS_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 75.9316 µV | D3 | SS_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 17.1016 µV | D4 | SS_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 16.7262 µV | D5 | SS_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 14.2648 µV | D6 | SS_LK_75.txt | Door open | Measured on 03/05/2021 |

Subject data report form ver 7.xlsx

**Figure D.2:** Subject 2 report form for skull simulator method

**Subject report form: Audibility study**

Subject ID: 3 Condition: SM (In-situ) / Artificial Mastoid / Skull Simulator Date: 3/15/2021

Born: 780411 Gender: Female / Male

Ear plug bilateral: Yes / No

Device brand / model: Intenso VC: 2 Gain: Max Other:

Agilent: Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

Callisto: REM module AC 40: Warble tones Subject intructions: Breathe calmly, no face mask

Skullsimulator: Ref 0.2 V/N Artificial mastoid: Without pad correction, $F_{DC}$ ~ 4N B&K2692: 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 0 | 5 | 10 | 25 | 20 | 35 | 40 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 0 | 5 | 5 | 0 | 15 | 15 | 10 | 35 | 40 | dB HL | |
| BC R | -10 | 0 | 5 | 0 | 0 | 5 | 20 | 20 | 20 | 25 | dB HL | |
| BC L | -10 | 0 | -5 | 0 | -5 | 5 | 10 | 10 | 20 | 20 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 3 threshold AC40 | 20 | 15 | 15 | 15 | 15 | 20 | 25 | 50 | 55 | 50 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 0.536 | 0.89 | 1.45 | 4.1 | 1.3 | 0.15 | 0.077 | 0.41 | 0.637 | 1.2 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/05/2021 |
| Subject 3 Supra threshold | 0.030 | 0.028 | 0.046 | 0.130 | 0.041 | 0.015 | 0.008 | 0.130 | 0.201 | 0.379 | ~~µVrms~~ / mVrms | +30 dB , Subject 3 supra threshold based on subject 1 supra threshold |
| MPO | 8.3 | 35.1 | 66.8 | 93.4 | 27.4 | 10.1 | 5.5 | 3.9 | 1.85 | 1.32 | mVrms | Measured on 03/05/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 15.9082 µV | D1 | SS_AUD_55.txt | Door open | Measured on 02/25/2021 |
| 2 | ISTS 65 dB SPL | 18.2516 µV | D2 | SS_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 75.9316 µV | D3 | SS_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 17.1016 µV | D4 | SS_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 16.7262 µV | D5 | SS_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 14.2648 µV | D6 | SS_LK_75.txt | Door open | Measured on 03/05/2021 |

Subject data report form ver 7.xlsx

**Figure D.3:** Subject 3 report form for skull simulator method

**Subject report form: Audibility study**

**Subject ID:** 4 **Condition:** SM (In-situ) / Artificial Mastoid / Skull Simulator **Date:** 3/15/2021

**Born:** 880418 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | 0 | 5 | 5 | 5 | 0 | -5 | -5 | -5 | -5 | -5 | dB HL | From Audiogram without ear plugs |
| AC L | 0 | 5 | 5 | 0 | 5 | -5 | 5 | 5 | 0 | 0 | dB HL | |
| BC R | -5 | 0 | 0 | 5 | 5 | 5 | 5 | 5 | -10 | -10 | dB HL | |
| BC L | -5 | 0 | 0 | 0 | 10 | 5 | 10 | 5 | -10 | -10 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 4 threshold AC40 | 15 | 15 | 20 | 10 | 15 | 15 | 20 | 25 | 25 | 20 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 0.536 | 0.89 | 1.45 | 4.1 | 1.3 | 0.15 | 0.077 | 0.41 | 0.637 | 1.2 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/05/2021 |
| Subject 4 Supra threshold | 0.017 | 0.028 | 0.082 | 0.073 | 0.041 | 0.008 | 0.004 | 0.007 | 0.006 | 0.012 | ~~µVrms~~ / mVrms | +30 dB , Subject 4 supra threshold based on subject 1 supra threshold |
| MPO | 8.3 | 35.1 | 66.8 | 93.4 | 27.4 | 10.1 | 5.5 | 3.9 | 1.85 | 1.32 | mVrms | Measured on 03/05/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 15.9082 µV | D1 | SS_AUD_55.txt | Door open | Measured on 02/25/2021 |
| 2 | ISTS 65 dB SPL | 18.2516 µV | D2 | SS_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 75.9316 µV | D3 | SS_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 17.1016 µV | D4 | SS_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 16.7262 µV | D5 | SS_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 14.2648 µV | D6 | SS_LK_75.txt | Door open | Measured on 03/05/2021 |

Subject data report form ver 7.xlsx

**Figure D.4:** Subject 4 report form for skull simulator method

## Subject report form: Audibility study

**Subject ID:** 5 **Condition:** SM (In-situ) / Artificial Mastoid / <u>Skull Simulator</u> **Date:** 3/15/2021

**Born:** 670503 **Gender:** Female / Male

**Ear plug bilateral:** Yes / No

**Device brand / model:** Intenso **VC:** 2 **Gain:** Max **Other:**

**Agilent:** Power Spectrum, 100-12.9k Hz, 40 averages, Hanning window, AC coupling, Autorange, Floating input, State saved as AUD_BIL.STA

**Callisto:** REM module **AC 40:** Warble tones **Subject intructions:** Breathe calmly, no face mask

**Skullsimulator:** Ref 0.2 V/N **Artificial mastoid:** Without pad correction, $F_{DC}$ ~ 4N **B&K2692:** 10-10k Hz, 10m V/ms^-2, 3400 pC/ms^-2

| Audiogram | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AC R | -10 | 5 | 5 | 5 | 5 | 5 | 10 | 10 | 10 | 20 | dB HL | From Audiogram without ear plugs |
| AC L | -5 | 0 | 0 | 5 | 5 | 0 | 5 | 5 | 10 | 5 | dB HL | |
| BC R | -5 | 10 | 5 | -5 | 0 | -5 | 5 | 5 | 0 | -5 | dB HL | |
| BC L | -5 | 10 | 0 | -5 | -5 | 5 | 10 | 0 | 0 | -5 | dB HL | |

| SF Threshold and MPO | 250 | 500 | 750 | 1000 | 1500 | 2000 | 3000 | 4000 | 6000 | 8000 | Hz | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Subject 1 threshold AC40 | 15 | 15 | 15 | 15 | 15 | 10 | 15 | 30 | 35 | 30 | dB HL | Attenuator AC40 at threshold measured 03/01/2021 |
| Subject 5 threshold AC40 | 20 | 15 | 10 | 5 | 15 | 15 | 20 | 30 | 35 | 20 | dB HL | Attenuator AC40 at threshold measured 03/15/2021 |
| Subject 1 Supra threshold | 0.536 | 0.89 | 1.45 | 4.1 | 1.3 | 0.15 | 0.077 | 0.41 | 0.637 | 1.2 | ~~µVrms~~ / mVrms | +30 dB Measured on 03/05/2021 |
| Subject 5 Supra threshold | 0.030 | 0.028 | 0.026 | 0.041 | 0.041 | 0.008 | 0.004 | 0.013 | 0.020 | 0.012 | ~~µVrms~~ / mVrms | +30 dB , Subject 5 supra threshold based on subject 1 supra threshold |
| MPO | 8.3 | 35.1 | 66.8 | 93.4 | 27.4 | 10.1 | 5.5 | 3.9 | 1.85 | 1.32 | mVrms | Measured on 03/05/2021 |
| Attenuator AC40 at MPO | 70 | 80 | 80 | 80 | 80 | 85 | 90 | 90 | 75 | 60 | dB HL | Attenuator |
| SPL at MPO | 79.4 | 83 | 79.4 | 80.2 | 81 | 82.2 | 82 | 82.2 | 81 | 78 | SPL re 20 µ Pa | Lin10-20k, Fast |

| Measurement | | 100 Hz | Memory | File name | | |
|---|---|---|---|---|---|---|
| 1 | ISTS 55 dB SPL | 15.9082 µV | D1 | SS_AUD_55.txt | Door open | Measured on 02/25/2021 |
| 2 | ISTS 65 dB SPL | 18.2516 µV | D2 | SS_AUD_65.txt | Door open | |
| 3 | ISTS 75 dB SPL | 75.9316 µV | D3 | SS_AUD_75.txt | Door open | |
| 4 | Noise floor: HA (ON), Speaker not involved | 17.1016 µV | D4 | SS_NF_HA_SM.txt | Door closed | |
| 5 | Nosie floor : HA (Removed), Speaker not involved | 16.7262 µV | D5 | SS_NF_SM.txt | Door closed | |
| 6 | Leakage : HA (Removed), ISTS 75 dB SPL | 14.2648 µV | D6 | SS_LK_75.txt | Door open | Measured on 03/05/2021 |

Subject data report form ver 7.xlsx

**Figure D.5:** Subject 5 report form for skull simulator method