CHALMERS
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Bone conduction ankle audiometer

A tool for simple screening for superior canal dehiscence syndrome (SCDS)

Master's thesis in Electrical engineering, 30 HP

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Cover: Photograph of the finished prototype.

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Abstract

This thesis documents the process of developing and testing a prototype bone conduction transducer stimulator for ankle audiometry using the novel B250 transducer which is developed by the Biomedical signals and systems research group together with Ortofon A/S. The device is intended to be used for screening for conductive hyperacusis (heightened sensitivity to internal bodily sounds), a symptom of superior canal dehiscence syndrome (SCDS). SCDS originates from an opening in the temporal bone overlying the superior canal of the vestibular labyrinth and results in symptoms such as vertigo and conductive hyperacusis.

The project utilises the B250 bone conduction transducer and focuses on the development of a driver circuit and enclosure of a prototype ankle audiometer. Specifically, the device must have a signal stability and usability that is better than, or equal to pre-existing tools. Since the device is intended to be certified as a medical device, care was taken to comply with relevant standards. The device is required to be able to stimulate the patient at five different intensity levels with a pure tone of around 250 Hz where the B250 has its peak in frequency response. A secondary goal was to construct a method to attach the transducer to the patient at a constant force of 10 N.

The resulting prototype is able to stimulate at 244.7 Hz with harmonic distortions well within the margin of 6%. The signal is also within the margin of error for all the desired intensity levels (<1 dB FL). The circuit and batteries are enclosed within a small portable plastic box. For further improvement and simplification of the ankle audiometry method, a solution to construct a patient attachment is also proposed in the thesis.

Keywords: Bone conduction, audiometry, oscillator, vestibular diagnosis, SCDS, VEMP, ankle audiometry, power amplifier.

Acknowledgements

There are several people that have contributed to the success of this project. Firstly, the greatest of thanks is owed to our supervisor, Karl-Johan Fredén Jansson. A special thanks is also owed to Doctor Luca Verrecchia for his great enthusiasm and insight in the subject. We also want to thank Sabine Reinfeldt, Bo Håkansson and the entire division of signal processing and biomedical engineering for being very helpful and making us feel welcome. Lastly, we owe a great thanks to the Prototype Laboratory at Chalmers for help and advice in the construction of the device.

Benjamin Blomqvist & Maximilian Eliasson
Göteborg, May 2022

Glossary

Below is the list of acronyms and terms that have been used throughout this thesis listed in alphabetical order:

AC	Alternating Current
BJT	Bipolar Junction Transistor
BEST	Balanced Electromagnetic Separation Transducer
DC	Direct Current
DFT	Discrete Fourier Transform
LED	Light Emitting Diode
Op-Amp	Operational Amplifier
THD	Total Harmonic Distortion
CT	Computed Tomography
dB FL	Decibel Force Level RMS
dB HL	Decibel Hearing Level RMS
dB SPL	Decibel Sound Pressure Level RMS
FMEA	Failure mode and effects analysis
MDR	Medical device regulation
RETFL	Reference Equivalent Threshold Force Levels
SCDS	Superior semicircular Canal Dehiscence Syndrome
VEMP	Vestibular Evoked Myogenic Potentials

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1
Introduction

This chapter presents the fundamentals of the topic of the thesis as well as outlining the goals and limitations that has guided the work in the project.

1.1 Anatomy of the inner ear

The inner ear serves two important functions of the human body: hearing, and the sense of balance. The vestibular system consists of the semicircular canals, providing sense of rotation, and the otolithic organs, the saccule and utricle, providing sense of linear motion, as well as the cochlea where sound is received (illustrated in Figure 1.1).

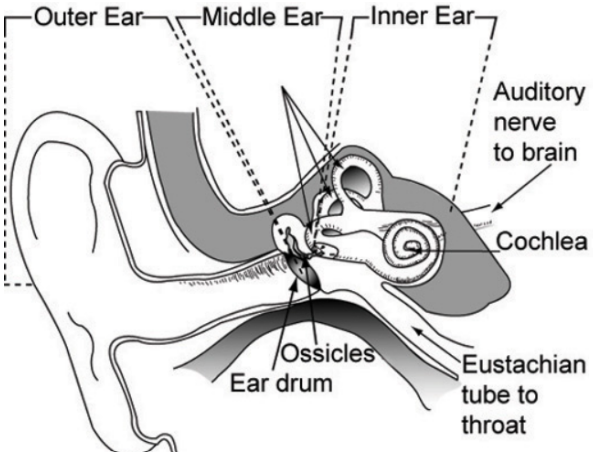

Figure 1.1: The anatomy of the ear (NASA, Public domain, via Wikimedia Commons)

1.2 Superior Canal Dehiscence Syndrome

In this section both the pathophysiology and the epidemiology of Superior Canal Dehiscence Syndrome (SCDS) is described.

Pathophysiology

A patient diagnosed with SCDS has a so called third mobile window, which is a small opening in the temporal bone overlying the superior canal of the vestibular labyrinth [2]. Symptoms of the syndrome include vertigo and vibratory induced nystagmus (Tullio phenomenon) [3].

Another symptom of SCDS, of particular interest for this project, is hypersensitivity to internal bodily sounds such as, eye movements and impact of feet whilst walking [3]. This is caused by an increased sensitivity to bone-conducted low-frequency sounds, a phenomenon called conductive hyperacusis. By surgically repairing the dehiscence, alleviation or control of the symptoms may be achieved.

Epidemiology

Roughly 2 % of specimens, as found in a study of cadavers, were at risk of SCDS, having a thinning of the temporal bone overlying the superior canal ($\leq$ 0.1 mm) [4]. Of those, roughly a quarter (0.5 % of the total specimens) had a complete dehiscence.

1.3 Diagnosis

A positive diagnosis of SCDS requires three criterions to be fullfilled. The patient needs at least one confirmed present symptom indicating a dehiscence, a positive physiological test and a radiological test in the form of high resolution, multi planar, computed tomography (CT) consistent with a dehiscence, to get a positive diagnosis [5]. The physiological test typically consists of demonstrating lowered vestibular-evoked myogenic potential (VEMP) thresholds and increased peak amplitudes [6].

1.4 Path to care

For a patient with self reported symptoms consistent with SCDS, the diagnostics process often starts with a screening [7]. The screening is conventionally done using a tuning fork which is struck then placed against the ankle of the patient. The patient is then asked to confirm if they can hear the tuning fork vibrations. This is intended to give the clinician a rough estimation of how severe the symptoms are. The tuning fork although simple lacks in repeatability and has no way of accurately measuring thresholds.

If the patient displays symptoms, consistent with SCDS, they are subjected to tests of the three criterion that are necessary to confirm the diagnosis [5]. If the patient shows positive results in all steps of diagnostics they are given a positive diagnosis.

Depending on the severity of the symptoms, and the degree of suffering that the patient experiences, the options are to continue living with the disorder or to undergo surgery [7]. The disorder is progressive and thus the patient may choose to undergo surgery later in life.

1.5 Purpose

The intention of this project is to develop a prototype of a bone conduction ankle audiometer that replaces the tuning fork when screening patients. The ultimate goal is to have a repeatable and statistically safe way of measuring the symptoms of SCDS patients. This will also be used as a way of evaluating the results of surgery in postoperative patients.

The project will concern the development of the driver circuit as well as the enclosure given the novel B250 bone conduction transducer. The driver circuits ability to control the bone conduction transducer will be technically verified to be within specific limits (see 1.7).

1.5.1 Specific goals

The above purpose is compressed to a set of specific goals which are listed below.

- Construct the device using as few and simple components as possible.
- Identify, and comply with, the most important requests/requirements of clinicians through interviews.
- Design a repeatable and easy to use patient attachment system.

1.6 Delimitations

Since a pilot study of SCDS patients and controls, using the device, would require an ethical approval from the Swedish Ethical Review Authority, which would take time to obtain, no such study can be performed in the scope of the project [8]. Rather, the only verification of the device that will be performed is bench testing to ensure the device functions as specified. The question whether the device may work in screening SCDS patients at a high enough specificity

and sensitivity will thus not be answered in this report.

Compliance with all applicable standards may not be confirmed in the scope of this project since that would require expansive testing. The standards are however taken into consideration during the design and development process.

The device developed in this project is intended to be used for pure-tone audiometry. In the case of ankle audiometry, a warbled signal has, however, generally been seen to be advantageous [7]. The warbling of the signal is left for future work and investigation.

1.7 Requirements

The device will have to heed to a set of requirements apart from the standards that are required to certify the device as a medical device. The requirements where mainly identified from interviews with leading researcher Dr. Verrecchia and apart from being easy to operate and mobile there are several more measurable requirements that are presented in Table 1.1 [9]. Crucially, the device should stimulate with a pure tone at a frequency of around 250 Hz and at six different intensity levels. The intensity is measured in decibels force level RMS (from here on referred to as dB FL).

Table 1.1: Identified technical requirements

	Requirement	**Accuracy**
Frequency	250 Hz	± 10 Hz
Battery life	10 hours	N/A
Weight	<1 kg	N/A
Stimulus Intensity Level	110, 115, 120, 125, 130, 140 dB FL	± 1 dB FL
Attachment force to patient	10 N	± 2 N
Battery powered (AA or AAA)	N/A	N/A

1.7.1 Requested functionalities

In addition to the product requirements, a number of requests were identified, some of which originate from safety concerns whilst some were raised by Dr. Verrecchia [9].

- Rechargeable battery.
- Not rechargeable during use.
- Wireless controls.
- The ability to cancel out one ear using pink noise.

2

Theory

This chapter describes the work that has been done prior to this project. The transducer is described in depth as well as the elements that will make up the prototype and other factors which need to be taken into consideration when designing the prototype.

2.1 Normal use case

For a normal screening using a tuning fork, the patient is firstly equipped with two earplugs and earmuffs and placed in a standardised soundproof booth [7, 10]. The ear of the opposing side of the ankle to be tested is also equipped with an insert earphone emitting narrow banded noise in order to cancel out the hearing of the non-test ear. The transducer is then applied to the medial malleolus with a force of 10 N.

The clinician begins by introducing the sound at 130 dB FL. At a positive response from the subject (the patient is able to hear the signal) the intensity is decreased by 10 dB FL [7, 10]. At a negative response (the patient can not hear the signal) the intensity is increased by 5 dB FL. By repeating the procedure up to three times, the threshold of hearing may be pinpointed to a level within 5 dB FL. If the patient has a threshold below 125 dB FL they are deemed to have symptoms consistent with SCDS [5].

2.2 BEST transducer

The B250 electroacoustic transducer is of the type balanced electromagnetic separation transducer (BEST) which means that the transducer has a different configuration of windings and permanent magnets compared to a conventional variable reluctance type transducer [1]. Instead of one single permanent magnet in the centre of the coil the BEST type has 4 permanent magnets in the corners of the coil, as can be seen in Figure 2.1, that create a balance in its air gaps cancelling non-linear and static forces. The advantages of using a BEST type transducer is that the vibratory force is linearly dependant on the dynamic and static magnetic flux of the transducer. The static flux stems from the permanent magnets and the dynamic flux is induced by passing an alternating current (AC) through the coil. In a variable reluctance type transducer the force is depending on the square of both of the flux parameters.

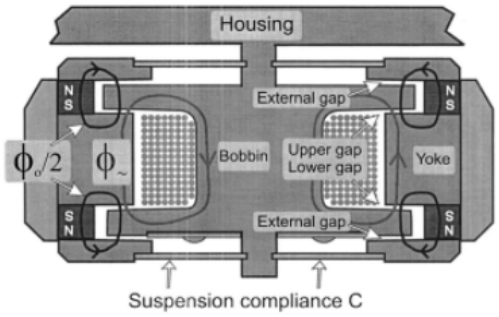

Figure 2.1: Cross-sectional view of the BEST. Used with permission of the author. [1]

The quadratic behaviour of the variable reluctance type transducers induces high harmonic distortions at relatively low frequencies [11]. The BEST principle removes the quadratic behaviour and with that the high distortions at low frequencies [1].

2.2.1 B250 transducer

The motor unit of the B250 transducer is based on the BEST principle [11]. The relatively large mass of the B250 results in a resonance frequency around 250 Hz [12]. Furthermore, in order to maximise contact and thus smooth transmission of vibrations, the surface, in contact with the subject, of the B250 is relatively large and concave [12, 13]. The total vibrating force F_{tot} of the B250 transducer is approximated as

$$F_{\text{tot}} \propto 4\Phi_{\text{o}}\Phi_{\sim} \tag{2.1}$$

where Φ_{o} is the static magnetic flux from each permanent magnet and $\Phi_{\sim}$ is the induced dynamic magnetic flux [1].

The electrical impedance of the B250 is plotted in Figure 2.2 using data measured data provided the department.

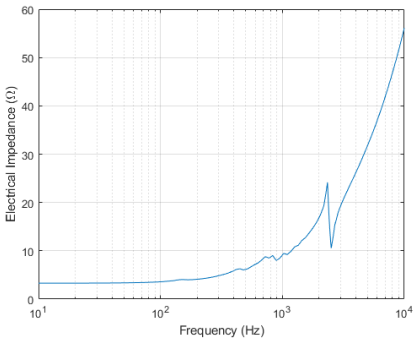

Figure 2.2: Electrical impedance of B250, measured at 10 mA_{RMS}

The frequency response of the B250 transducer is plotted in Figure 2.3 using data provided by the department [13]. The peak of the frequency response is then found to be at 240 Hz.

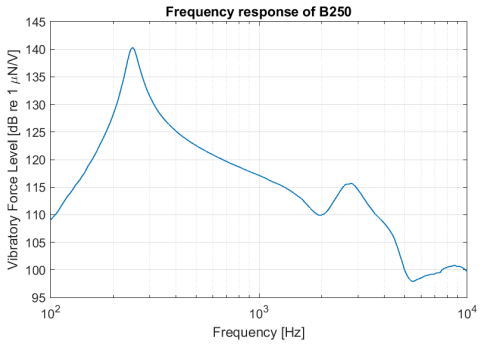

Figure 2.3: Frequency response of B250, measured at 0.1 V_{RMS}

2.3 Transducer power supply

The theoretical background for the full circuit that is needed to construct the transducer power supply is detailed below and the different elements are illustrated in Figure 2.4.

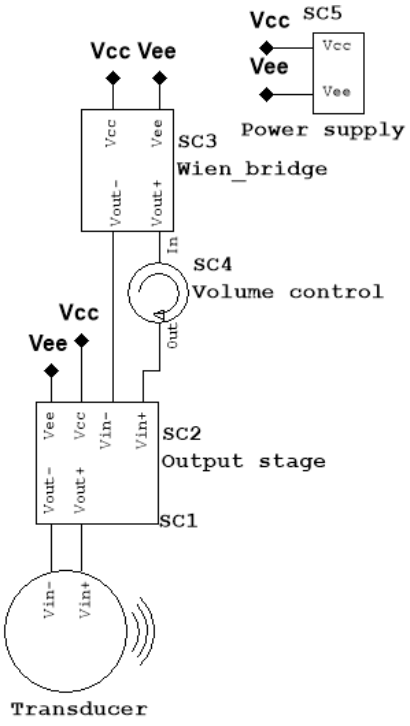

Figure 2.4: Concept of the driver circuit

2.4 Power supply circuits

The power supply generally consists of some sort of galvanic isolation and often some protective circuits such as reverse polarity protection.

2.4.1 Reverse polarity protection

For any device powered by a polarity dependent source (eg. direct current (DC)) one may safeguard it from the effects of the polarity of the input source being reversed. For DC inputs a circuit protection may be realised by implementing a full bridge rectifier using four diodes according to the configuration shown in Figure 2.5. This ensures that the direct current always flows from positive to negative, and not the opposite which might damage some components, regardless if the source is connected the wrong way [14, pp. 208-209]. Another solution would be to simply put a rectifier diode with a high reverse bias threshold. This would only ensure that there is no flow of current if the source is reversed.

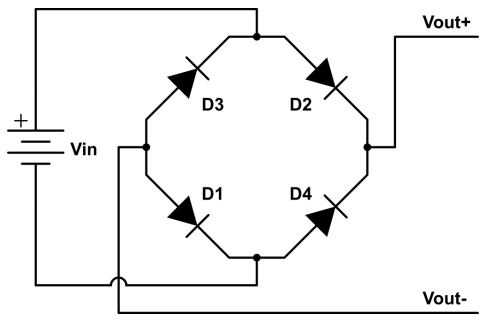

Figure 2.5: Reverse polarity protection circuit

2.4.1.1 Isolated DC-DC conversion

For medical devices connected to sources that are capable of delivering currents that may be harmful to humans it is a good idea to separate the input from the output through galvanic isolation [15]. This is generally achieved with a power inverter connected to a transformer followed by a rectifier circuit [16]. It is also a requirement for "line powered" devices [17]. For low power devices it provides a good extra layer of protection for the circuit by adding inertia which will prevent large transients in current [16]. Another upside of DC-DC converters is that they generally have a floating output. The output is floating in the sense that it maintains a constant voltage output regardless of input voltage fluctuations within a certain range [18]. Another benefit of the converter is that it may improve the noise immunity of the circuit by limiting what passes through it.

2.5 Wien bridge oscillator

In broad terms oscillators are circuits that require no input power to produce a non constant output signal. All that is necessary is a supply voltage. A common oscillator circuit is the Wien bridge oscillator which is an amplifier circuit (shown in fig. 2.6) that need to be unstable to begin oscillating and has to be marginally stable in order to maintain oscillations [19]. Satisfying this is called the Barkhausen criterion. If the gain is close to unity it is possible for the system to oscillate with very limited distortions and when the gain is increased the signal will not go to infinity but instead it will be clipped due to the limited supply power [14, pp. 1174-1177]. The Wien bridge is hence capable of producing a sine wave output without any input signal. The Wien bridge is one of the most commonly used oscillators and it's properties include good frequency stability and relatively few components.

By setting $R_1 = R_2 = R$ and $C_1 = C_2 = C$ the circuits natural frequency, $\frac{\omega_0}{2\pi} = f_0$, is

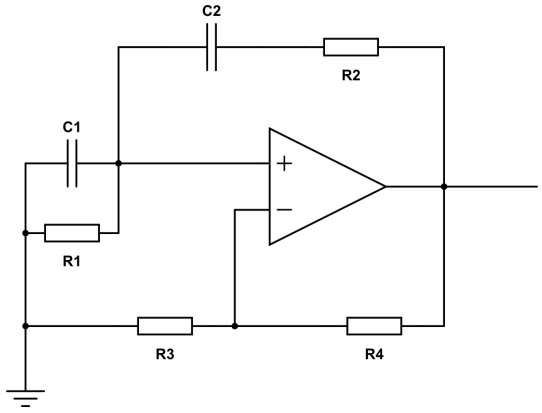

Figure 2.6: A Wien bridge oscillator

calculated as

$$f_0 = \frac{1}{2\pi RC} \tag{2.2}$$

and by doing so the gain of the system also loses its frequency dependency [19]. Thus the Barkhausen criterion may be reformulated and it can be stated that the system will become unstable and hence oscillate when the gain, calculated as $1+\frac{R_4}{R_3}$, is greater than three [14, pp. 1174-1177]. When the gain is exactly equal to three, the system will be marginally stable and the distortions of the output signal will be minimised.

2.6 Power amplification

As the transducer is of very low impedance ($\sim 4\Omega$) at the desired frequency it is not possible to connect it directly to the output of the Wien bridge oscillator. This is due to the low output power of the Wien bridge despite its relatively high output voltage. The most common method for solving that type of issue is to connect the output signal to a power amplifier in order to separate source and load circuits with large differences in impedance [20, pp. 1103-1115]. This is also referred to as impedance matching. In this implementation it is necessary to impedance match in order to get a large enough current to flow through the transducer.

Most analogue amplifiers utilise transistors to amplify the current. For a non-ideal transistor there is a threshold voltage, V_{cutoff}, at about 0.7 volts that needs to be surpassed in order to make the transistor conduct [20]. This means that all transistors have a deadband from zero to its threshold. After that the output voltage is proportional to the difference between the input and threshold voltage.

As a means to combat the non ideal properties of the transistors one can create a class AB power amplifier, that consists of Bipolar Junction Transistors (BJT) (illustrated in Figure 2.7) [21]. The NPN transistor will mainly push current onto the load when the input voltage is positive and the PNP transistor will mainly pull current the other way when the input voltage is negative [20]. By connecting the DC supply power to the input side of the amplifier there will always be current passing from V_{cc} to V_{ee} via the resistors (R_1, R_2) and diodes (D_1, D_2) [21]. With a nonzero current flow through the diodes, the voltage drop, V_{diode}, will be constant. V_{diode} is generally, roughly equal to the threshold of the transistors. When calculating the resulting voltage at the base of the transistors compared to the input signal it is clear that the signal will be offset from the input by $\pm V_{diode}$. By choosing diodes with a higher voltage threshold than the transistors it is ensured that the transistors will conduct for slightly more than a half cycle of the input signal. If the diodes are exactly matched to the transistors the transistors will stop conducting at exactly 0 volts on the input signal, V_{in}.

The resistors in the class AB power amplifiers work mainly by restricting the current which increases the efficiency of the amplifier. If they are chosen too small, a lot of the current will pass through the input side of the amplifier and thus reducing the amplification of the signal. If they instead are too large, there will not be a high enough cur-

rent to turn make the transistors conduct and the signal will be heavily distorted. Due to the non-ideal characteristics of the components the values has to be decided upon experimentally.

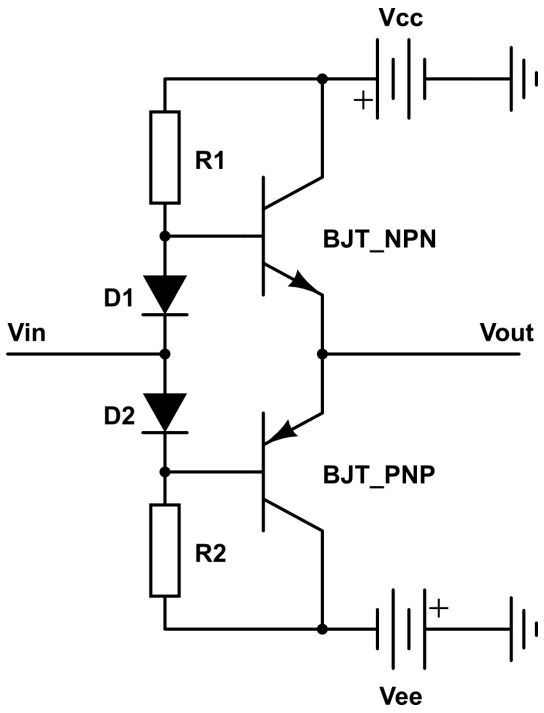

Figure 2.7: Class AB power amplifier

2.7 To measure bone conducted sound

When measuring air conducted sound, the sound intensity is generally described in terms of decibels sound pressure level (dB SPL) which is a measure of the sound pressure intensity relative to 20 µPa [22]. This scale has since been translated into decibels hearing level (dB HL) which is normalised such that 0 dB HL is the nominal hearing threshold at every frequency. When using a bone conduction device to transmit sound, the amplitude is often described as units of decibels force level (dB FL) which is calculated as

$$F_{dB} = 20 \log_{10} \left(\frac{F}{1\mu\text{N}} \right). \qquad (2.3)$$

The measured force, F, is expressed in Newtons (N), and the calculated force, F_{dB}, in decibels relative 1 µN. According to ISO 389-7:2019 the force level may be related to the decibel hearing level through a curve of varying coefficients for different frequencies [22]. Hence one may calibrate an audiometer using the reference equivalent threshold force level (RETFL) curve.

2.8 Electromagnetic compatibility (EMC)

To ensure that the device is safe from malfunction or harm due to electromagnetic interference (EMI), it is necessary to use some protective measures [23]. The isolating dc-dc converter in the input stage provides some protection from disturbances generated in the power source by breaking up eventual ground loops.

Another way to safeguard the device is to shield exposed electronics with grounded enclosures [24]. This could, for example, mean that the cables and the device itself is enclosed in metallic shields connected to ground.

2.9 Enclosure

The enclosure is the only protection from physical damage to the circuit and must therefore ensure that the circuit is safe during normal conditions. As well as protecting the device it also needs to have space for all the necessary buttons, dials and outlets that are required to operate the device. By request, it should also have a minimal footprint in order to be portable [9].

2.9.1 Ingress protection

One important property of the enclosure is that it must protect the circuitry from ingress

of liquids and solids at a level that satisfies normal usage conditions [25]. For the case of ankle audiometry there is no significant risks of submersion in water or a lot of dust in the room that could harm the device [7]. As is evident from the normal use case (section 2.1), the enclosure only needs to be properly protected from larger solids such as fingers or tools. This would mean that the first numeral in the IP rating would be a 4, meaning protection from intrusion of objects with a diameter of one millimetre or larger.

The second numeral in the IP rating is protection against water and as the device only should be used in dry conditions it does not need a rating higher than 2 which means that it should stand up to water droplets falling on top of it [25, 7]. It is necessary to balance between a high enough rating such that the device works in the intended environment without imposing too high requirements since that might increase the production costs.

2.10 Patient attachment

During ankle audiometry, the transducer is to be attached and held in place against the malleolus of the patient with an approximate force of 10 N which is the pressure for which the sound levels are calibrated [10]. Stimulation at the ankle as well as the vertex of the skull and, the spinous process of the 7th cervical vertebra using a Minishaker has proven to yield good separation of hearing thresholds for SCDS patients and healthy subjects. The choice of designing the device for ankle stimulation is mainly due to ease of attachment at the malleolus along with the fact that the ankle is the stimulation site of the screening method using a tuning fork [7]. A tuning fork placed at the vertex of the skull or the spinous process of the 7th cervical vertebra would likely not yield any significant difference in hearing thresholds between SCDS patients and healthy subjects [10].

2.11 Testing and verification

This section describes the software and equipment used for testing and simulating different parts of the system.

2.11.1 Simulation software

Simulations of the circuits designed in this project were performed using the `Multisim` software which allows the user to construct and simulate circuit schematics using virtual constructions of actual commercially available components [26]. Additional simulations, testing and calculations were performed using `Matlab` [27].

2.11.2 Artificial mastoid

For testing, calibration and verification of the bone conduction device, the *Brüel & Kjær* artificial mastoid, type 4930, was used (see Figure 2.8). The artificial mastoid consists of inertial weights that simulate the human skull as well as a piezoelectric load cell that outputs a voltage proportional to the applied oscillating force [28]. In order to convert the output to a force measurement, the voltage may be multiplied with the pad correction factor at 250 Hz from [12, Fig. 4]. At the desired frequency, the pad correction is approximately 0.113 V/N. The artificial mastoid has a frequency range of 50 Hz to 10 kHz which is highly suitable for the implementation. The *Brüel & Kjær* mastoid also complies with the standard IEC 60318-6:2007 and especially part 6 which dictates standards for mechanical couplers intended for measurement on bone conduction devices [29].

Figure 2.8: The artificial mastoid used for testing

2.11.3 Total harmonic distortion

The total harmonic distortion (THD) is a measure of the total harmonic content relative to the magnitude of the signal at the fundamental frequency [30]. It can be said to be a measure of the purity of the signal. The THD for all nonzero harmonics is calculated, according to the standard IEC 60268-3, as

$$\mathrm{THD} = \frac{\sqrt{\sum_{n=1}^{N} V_n^2}}{\sqrt{V_0^2 + \sum_{n=1}^{N} V_n^2}} 100\ \% \qquad (2.4)$$

where V_0 is the RMS amplitude of the fundamental frequency component, V_n is the RMS amplitude of the nth higher harmonic frequency component, and N is the number of higher harmonics taken into account [31]. Devices intended for pure-tone audiometry must have THD less than 6%, calculated according to (2.4), as specified in standard IEC 60645-1 [32].

2.11.4 Other tools

When developing the device there are several other tools that are useful and necessary in the process. Firstly, DC and AC power supply are necessary to test the different parts of the circuit. A DC power supply (Micro support Laboratory-power supply) simulates batteries without the drawback of power decrease over time. Meanwhile, an AC source (Agilent 33220A function generator) can be used to test the transducer and amplifier stage by simulating the output from the oscillator circuit with very clean signals [33]. This tests if there are any unwanted harmonics or noise generated by the circuit.

Measurements of the system can be made in many ways and with many tools. Signal display and recording is easily done with a Picoscope, digital oscilloscope [34]. It is also a good way of measuring the output amplitude. For this type of measurements the sampling rate does not need to be very high as there are other tools better suited for frequency analysis such as an Agilent 35670A, dynamic signal analyser, which easily plots frequency spectrum and has the capability of automatically calculating the total harmonic distortion for the closest 40 harmonics, which is the upper limit of what the artificial mastoid can record (10 kHz) [28, 35].

For crude measurements and quick testing it is most common to use a multimeter (such as the Agilent U1253B) as they are quick to use and have many different modes [36]. The multimeter is in particular useful for measurements of voltage, current, and resistance in addition to tests of continuity. The current is necessary to measure in order to estimate energy consumption and to ensure that no circuits are overloaded. Measurements of current may be somewhat erroneous due to the added load of the internal resistance of the multimeter.

3
Methods

The following chapter describes the process of development and testing that was performed during the project.

3.1 Driver circuit design

The driver circuit for the transducer was designed and verified through simulations, calculations and testing. After each stage of the circuit was constructed, the signal was measured and the frequency content studied using the discrete Fourier transform (DFT). The methods of development are presented below. The whole circuit was realised on a perfboard in order to simplify future updates of the circuit.

3.1.1 Input stage

A DC-DC converter was purchased and installed at the input stage to provide galvanic isolation between the power supply and the driver circuit, and to ensure a floating input to the circuit.

3.1.2 Wien bridge oscillator

Based on the general Wien bridge depicted in Figure 2.6, a circuit for simulation was constructed in `Multisim 14.2`. The Wien bridge was chosen as the electrical oscillator due to the simplicity of the circuit, and the relative stability in frequency of the sine wave it produces. Using theoretically deduced values, based on the equations in section 2.5, for the parameters, simulations were performed and the parameters further tuned. To some degree, availability was also dictating the choice of components.

3.1.3 Intensity control

The intensity level of the output signal is adjustable using a rotary switch connected to resistors of varying resistance. The resistance values were chosen using simulations and testing with a potentiometer to ensure that each discrete step of the switch corresponded to one of the required force level outputs. The output force was measured with the *Brüel & Kjær* artificial mastoid. By using resistors as a means of current limiting there is no added distortion to the signal but there are larger losses in the system. Another method of control of stimulus intensity would have been to reduce the supply voltage of the oscillator circuit.

3.1.4 Power amplification

The output of the Wien bridge oscillator was connected, via the stimulus intensity controller, to a power amplifier circuit of class AB constructed according to the diagram in Figure 2.7. In simulation, a model of the B250 transducer, consisting of a resistor in series with an inductance, was used. This electrical analogue was connected to the output of the power amplification stage. The parameters of the modelled transducer were based on previous measurements, plotted in Figure 2.2. At 250 Hz the total impedance was $\sim$4.43 Ω out of which 3.2957 Ω is resistive load.

The circuit was then realised on a breadboard and tested both with a signal generator and the Wien bridge oscillator. The output was measured both with and without the transducer. When the transducer was not connected the output voltage was measured and otherwise the output voltage from the artificial mastoid was measured. Lastly it was moved to the perfboard and tested with the Wien bridge and transducer to verify that nothing had changed from earlier tests.

3.1.5 Testing and prototyping

The driver circuit was simulated in `Multisim` before construction. In order to streamline the process, the separate elements of the circuit were modelled as subcircuits which can be seen in Figure 2.4 as separate labelled blocks. By doing so, unit testing of the different blocks is considerably easier.

When the simulations of a subcircuit were producing sufficient results, it was constructed on a breadboard and tested. For all testing a DC bench power supply was used to power the operational amplifier in the oscillator, and the transistors in the power amplifier. The output signal from each subcircuit was studied using a digital oscilloscope as well as a dynamic signal analyser [34, 35]. The power amplifier was initially tested using a signal generator which could produce clean sinusoidal signals at 250 Hz and it was also tested with the B250 transducer and the artificial mastoid [33]. Eventually, when the current subcircuit on the breadboard fulfilled the requirements put on it, it was moved to a more permanent location on a perfboard.

For technical verification with the transducer, the *Brüel & Kjær* artificial mastoid, type 4930, was used [28]. The reason for using the mastoid was not to find the force/hearing thresholds as stimulation in the normal use case is done on the ankle and not on a mastoid. Instead the mastoid was used as a purpose built force gauge. The focus of the technical verification was to ensure that the transducer driver circuit produces controllable output levels within the specified margins (from table 1.1).

A toggle switch was chosen to switch the mains power on and off, whilst a momentary push button was chosen to trigger stimulation. The device should not be left stimulating for too long, since that may damage the transducer; a momentary switch minimises the risk of that happening. Each switch was also connected to a LED to signal to the user when the switch is in the on position. Using the multimeter, the current from the batteries during normal usage was measured.

3.2 Enclosure

Due to the low power implementation it was deemed that a grounded enclosure was not necessary and one with more electrically insulating properties could be chosen. When it became apparent what needed to fit inside the enclosure a plastic box was ordered. In order to have it protected from intrusion and damage it was necessary that the box had a lid that could be screwed on.

In order to accommodate for the switches and outputs necessary to operate the device seven holes had to be made. Two of them were for the LED indicators, one was for the 6 mm stereo jack, one for the controller of stimulus intensity and two for the stimulation and main power switch. The last hole was a larger square hole that was milled on the side of the enclosure to accommodate the battery holder.

Due to the size of the battery holder combined with the limited space in the box the main power switch had to be placed on the backside and the stimulus intensity control

knob had to be placed more to the middle compared to the sketch in Figure 3.1.

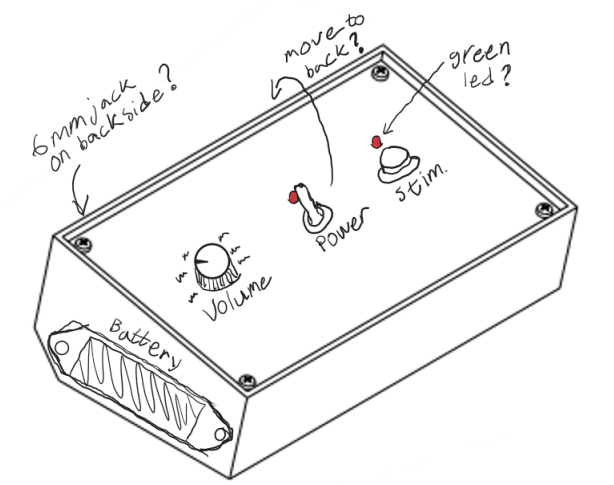

Figure 3.1: Design Concept

3.3 Patient attachment

A number of solutions to the patient attachment, in particular with regard to the problem of ensuring 10 N force applied, were investigated but ultimately not constructed. The final suggestion for construction landed in a spring loaded socket in which the transducer sits. The motivation behind having all force gauging properties attached directly to the transducer is to remove the need for a specific way of attaching it to the patient as well as increasing the measuring accuracy.

3.4 Risk analysis

As a means to mitigate any obvious hazards a Failure Mode Effects Analysis was performed [37]. This type of analysis studies the effects of something malfunctioning with the device. The ultimate goal is to identify failure hazards that need to be mitigated in the design of the device. First the possible failure modes and their outcomes are theorised. Then the likelihood and severity is estimated on a 5 degree scale.

4

Results

This chapter presents the results of the development process as well as findings that are later to be discussed.

4.1 Driver circuit

The driver circuit was constructed in parts according to the different subcircuits illustrated in Figure 2.4. This section describes the results from the construction of these subcircuits.

4.1.1 Wien bridge oscillator

The Wien bridge oscillator was constructed according to the circuit schematic depicted in Figure 2.6 with the parameter values presented in table 4.1. The output, plotted in Figure 4.1 shows very stable oscillations and when studying the DFT in figure 4.2 the main frequency is found at 244.7 Hz with very little disturbance. The output voltage is also stable.

Table 4.1: Component values for Wien bridge oscillator

Component type	Component label	Impedance or component no.
Trimmer potentiometer	R_3	~50 Ω
Operational Amplifier	OP_Amp	UA741CP
Resistor	R_1, R_2	92 kΩ
Capacitor	C_1, C_2	6.8 nF
Resistor	R_4	100 kΩ

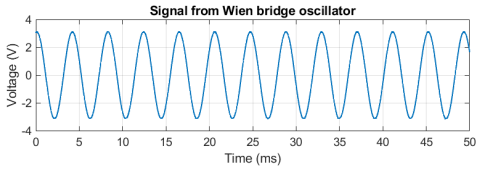

Figure 4.1: Output signal from Wien bridge

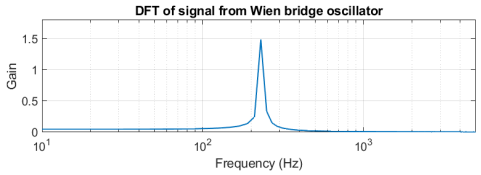

Figure 4.2: DFT of output from Wien bridge

4.1.2 Stimulus intensity control

The stimulus intensity controller was constructed with six stages using a rotary switch and in table 4.2 the resistances and their corresponding output force levels are described. The increment of 5 dB FL per step was requested by Dr. Verecchia and the 140 dB FL stage is a means of giving some overpower to the device for additional testing [9]. Normally, no levels above 130 dB FL will be used.

Table 4.2: Resistor values for stimulus intensity controller

Stimulus intensity level [dB FL]	Resistance [kΩ]
110	20.2
115	12
120	6.2
125	2.8
130	1.5
140	0.180

4.1.3 Power amplification stage

The amplifier was constructed according to the diagram in Figure 2.7 with the components listed in table 4.3. By connecting the power amplifier to the output of the Wien bridge oscillator the unloaded output voltage was measured and is pictured in Figure 4.3 and the corresponding DFT can be seen in Figure 4.4.

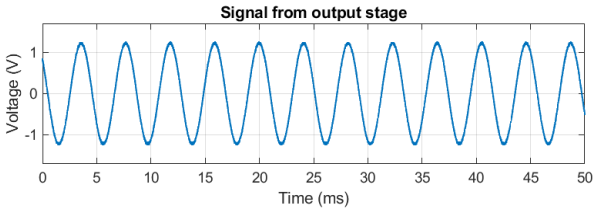

Figure 4.3: Signal from Wien bridge through output stage

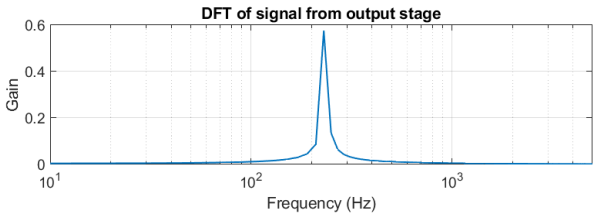

Figure 4.4: DFT of output signal from Wien bridge through output stage

Table 4.3: Component values for output stage

Component type	Component label	Value/ Component no.
Transistor	BJT NPN	2N4401
Transistor	BJT PNP	2N4403
Diode	D_1,D_2	1n4148
Resistor	R_1,R_2	10kΩ

4.1.4 General performance

With the entire driver circuit completed, the performance, regarding THD, accuracy of stimulus intensity, and frequency accuracy, of the device was tested using the artificial mastoid. The actual intensity levels produced by the device and measured by the mastoid, are displayed in comparison with the target levels in table 4.4. The THD of the output signal from the artificial mastoid was measured at each discrete level of stimulus intensity. The results are displayed in table 4.5. It is worth to note that the THD is not taking the pad correction of the *Brüel & Kjær* artificial mastoid into consideration.

Further, the output signal from the artificial mastoid at 130 dB FL is plotted in Figure 4.5. The DFT of the same signal can be seen in Figure 4.6.

Table 4.4: Target intensity and actual intensity

Target intensity [dB FL]	Actual intensity [dB FL]	Deviation [dB FL]
110	110.14	0.14
115	114.73	0.27
120	119.97	0.03
125	125.92	0.92
130	130.22	0.22
140	139.28	0.78

Table 4.5: THD performance

Stimulus intensity [dB FL]	THD [%]
110	0.088
115	0.095
120	0.128
125	0.175
130	0.305
140	1.636

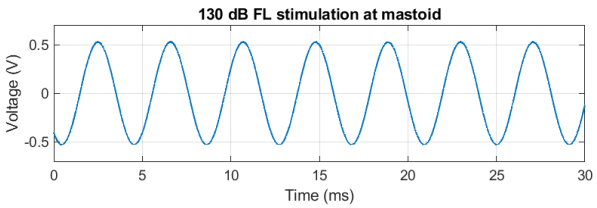

Figure 4.5: Output signal from artificial mastoid at 130 dB FL

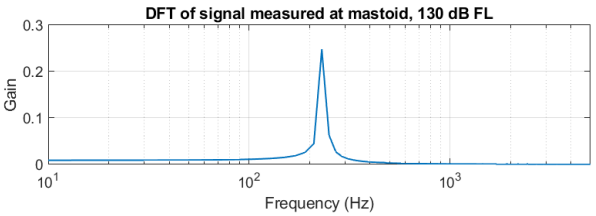

Figure 4.6: DFT of output signal from artificial mastoid at 130 dB FL

With the device switched on but not stimulating, a current of around 100 mA was measured from the batteries. When stimulating at the highest intensity the current measured was 280 mA. Assuming a battery capacity of 2500 mAh, the maximal battery life is thus 25 hours and the minimal around 9 hours.

4.2 Enclosure

The enclosure was constructed as described in section 3.2 and the final prototype is pictured in Figures 4.7 and 4.8. On the back the mains power switch is located with an indicator LED as well as the 6 mm stereo socket. on the top side of the enclosure, the momentary stimulator button is found with yet another indicator LED and is the accompanied by an intensity level controller. The device weighs less than 1 kg.

Figure 4.7: Front view of the device

Figure 4.8: Back view of the device

4.3 Patient attachment

For the patient attachment one main solution is proposed. It consists of a socket with a spring at the bottom which connects to the back of the B250 transducer as illustrated in Figure 4.9. On the side of the socket there is a hole that will be completely covered by the transducer when 10 newtons of force is applied in order to give the clinician a visual confirmation of when the force is at the right level. The socket could be attached to the patient with either a strap or a clamp and the same results would be achieved. The hole could also be replaced by making the transducer close two leads and turn on a LED at 10 N.

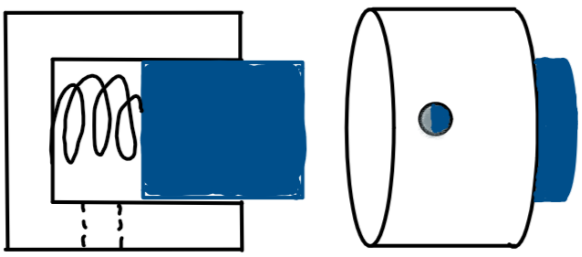

Figure 4.9: Conceptual sketch of suggested mechanical solution

4.4 Risk analysis

After most of the prototype was constructed and tested in a laboratory environment, a safety analysis was performed in order to identify any flaws that would need rectifying in the next prototype. The method of analysis was a failure modes and effects analysis (FMEA) and the results are shown below in table 4.6.

The biggest concern was that the signal might change without the operator knowing. The potential changes could be several, more distortion, frequency changing or amplitude dropping or rising.

Table 4.6: FMEA of prototype

Identification of hazardous situations	**Harm**	**Severity (1-5)**	**Probability (1-5)**	**Estimation of the risk of the hazard**	**Risk control option analysis**
Signal different from what operator thinks	May induce pain if intensity too high	4	1	II	Hardware limit on power output
	May result in an incorrect screening result if intensity or frequency changes	2	3	II	Regular calibration/ controls
Prolonged use	May damage skin	1	2	I	Supply information in manual
Liquid ingress of enclosure	Device malfunctions, minor risk of shock	1	2	I	Better IP classification

I	Mostly acceptable. Risk control measures not necessarily needed.
II	Risk control measures needed
III	Unacceptable. Risk control measures mandatory

5
Discussion

In this chapter the methods, testing and results are discussed. Additionally, the chapter deals with ethical and ecological considerations along with identified possibilities for future development and studies.

5.1 Methods

When developing the prototype there were some solutions that were chosen out of necessity and could have been evaluated more carefully. One of those things is the Wien bridge oscillator. There are several other simple oscillator circuits that possibly could have performed better or have been simpler in its construction. The Wien bridge was chosen for its acclaimed stability but no other types of oscillator were actually tested.

Many of the chosen solutions and circuits stemmed from an idea or goal to make the final product as cheap to produce as possible. This is the main motivation for not using any digital components. By going analogue all circuits are easily produced with standardised components and the device is also much more easily repaired.

5.1.1 Testing

Most of the testing performed in the lab environment have served to verify the technical requirements. The tools and methods used have in general been very well suited to do that. Yet it is obvious that further studies must be done to verify that the technical performance translates into good diagnostics and a tools that actually does what it is intended to do. This is best done as a small scale pilot study to test usability followed by a larger study that actually evaluates the devices diagnostic capabilities.

The artificial mastoid used for testing of the device may not have been a perfect analogue to a patient's malleolus where the transducer is supposed to stimulate. The differing shape of each bone may result in a different contact surface and the signal being transferred inconsistently. By designing an adapter shaped specifically to the malleolus and attaching it to the transducer, the energy transfer may be maximised.

Furthermore there has only been limited amounts of testing to ensure that the prototype follows the identified standards from section 1.7. Of the relevant standards, the prototype has only been ensured to adhere to the standard of total harmonic distortion. The total harmonic distortion is also not calculated with the pad correction of the artificial mastoid in mind which could alter the results slightly. Much of the designing and developing has taken the standards into account but there has been no explicit testing to ensure that the device complies with them. The underlying motivation for identifying these standards was to ensure that the finished device could build upon the developed prototype and to adhere to most of the standards without making any large changes.

5.2 Performance

In this section the performance of the device is discussed and suggestions for future work is brought up.

5.2.1 Distortion

As seen in table 4.5, the device is able to produce a pure sinus wave with low levels of THD at the artificial mastoid of 1.82 % in the worst case (at the highest intensity level of 140 dB FL), which is far below the threshold of 6 % described in IEC 60645-1. As the THD increases in an exponential manner it is possible that the increase is a result of the transducer moving around on the mastoid and not a fault in the electrical signal. This is further enforced by studying the DFTs of the electrical signals from the power amplification stage and the Wien bridge.

5.2.2 Frequency and stimulus intensity

The frequency of the signal is, at 244.77 Hz, close to the original target of 250 Hz which for the purpose of the device is more than good enough. If the specific frequency of 250 Hz is desired, some tuning of the resistors R_1 and R_2 in the Wien bridge oscillator should be performed.

The stimulus intensity level of the signal measured at the artificial mastoid deviate somewhat from the target intensity levels as seen in Table 4.4 but are well within the specified limits from Table 1.7. The intensity accuracy may be further tuned by changing some of the resistors in the intensity control. One step to further improve the intensity accuracy would be to add low impedance (within 1 kΩ) potentiometers to each intensity stage in order to further tune them.

5.2.3 Battery life

A battery life of between 9 and 25 hours is definitely sufficient for the device. Furthermore, the battery life could be lengthened by placing the stimulation switch at the output of the DC-DC conversion stage. Thus, neither the oscillator nor the power amplifier will consume power whilst the device is switched on but not stimulating. However, that would mean that there may be some transients from the oscillator right after the stimulation switch is pressed which could compromise the examination.

5.3 Power supply

The device is sufficiently powered with four AA batteries, and the implementation of the input stage ensures that the Wien bridge and power amplifier both are supplied with a stable ±5 V. This entails that as long as the batteries supply a voltage within the range of the DC/DC converter the device will work as intended. As an area of improvement it would be of high interest from a financial/business perspective to invest time in developing a solution for rechargeable batteries to be used.

5.4 Ethical considerations

In this section, several different aspects of ethics and sustainable development is discussed. The primary ethical consideration of the device is the improvement of SCDS diagnosis and subsequently SCDS patients' quality of life. By introducing a simple and accurate diagnostic method using the device, clinicians may diagnose patients accurately at a higher rate and provide them with suitable treatment earlier. Furthermore, an improvement to the existing ankle audiometry using a tuning fork, would result in fewer false positives needing to un-

dergo the costly and time consuming CT diagnosis. This might reduce the waiting times for patients in need of CT.

5.4.1 Ecology

When developing a new product there are always a large amount of ethical questions to consider. One that is important for all products, and not just medical devices, is the question of ecological impact.

Already in the prototyping stage there are lots of things that may be done to make the final product as ecologically sustainable as possible. That could for example include minimisation of materials used per unit and smart choices of materials to reduce waste. it is also important to consider the whole life cycle of the product to maximise recyclability when the product is discarded.

Another ecological consideration is the use of electronics containing rare earth metals that are present in many common electronics. This is a great motivation for minimising the number and complexity of components in the device but entails specific tuning of the oscillator as it is designed now. By doing this, the need of some metals that come with microcontrollers and other digital components are reduced.

5.4.2 Safety

One of the biggest concerns when developing products for the medical industry is the safety of patients and clinicians. This is very well regulated in the MDR and by adhering to the harmonised standards all devices should be considered safe to use in a clinical setting. So for a finished product there are no safety considerations to be made apart from the ones enforced by regulations.

It is when the device is to be tested that there needs to be other precautions made. Most importantly must the device be tested properly in a lab environment to ensure that if it fails, it fails in a way that will not harm patients or clinicians. After that it is important to adhere to the WMA Declaration of Helsinki which states ”ethical principles for medical research involving human subjects” [38]. That means that the study must take extra measures to ensure patient safety and autonomy. For it to be allowed to perform studies on human subjects in Sweden it is also necessary to have an ethical approval from the Swedish Ethical Review Authority [8].

5.5 Future work

There are a number of ways to improve and add to the prototype in the future. Primarily, the patient attachment stage should be a priority in future work to ensure the device may be tested in a clinical setting.

Although the device has been proven to work in a lab setting it is important that a pilot study is performed to ensure that the device works safely on patients. After that a larger study should follow with a mix of healthy subjects and subjects with confirmed SCDS to determine its efficiency at screening subjects.

In previous studies a warble tone has been used in contradiction to what the prototype produces. This entails that a study has to be performed that verifies that ankle audiometry with a pure tone provides equivalent results in comparison to warble tone audiometry. If it does not, then a method for warbling the tone must be developed. This could either be an addition to the existing prototype or a completely new prototype. It is suspected that warbling the tone is easier to implement in a digital signal generator.

Another important aspect of product development and further utility of the device would be to develop a solution which have

the capability of switching the frequency in order to screen for or diagnose several other conditions. For example could the device screen for Ménière's disease if a patient comes in during a dizzy episode. For this implementation no changes to the driver circuit would be necessary as the patients generally suffer from hearing loss primarily in the lower frequencies. With changed frequencies (100 Hz and 400 Hz) one could do so called Skull Vibratory Induced Nystagmus (SVIN) tests to assist diagnosis of unilateral vestibular loss [39]. Which is an asymmetric loss of vestibular function. For this one would need to change the frequency of the Wien bridge by altering the resistances or capacitances and at the same time would the stimulus intensity levels need to be changed such that the desired levels are achieved. This could be achieved by having two or more Wien bridges with their own amplitude controllers on separate printed circuit boards and a switch which chooses what input is connected to the amplifier.

The list of requests in Section 1.7.1, have not been thoroughly investigated. For example, a pink noise generator, to cancel out the ear that is not subject to the test, could be incorporated into the device. For further development all of the requests should be evaluated. No request is necessary for the operation of the device but they could all be good additions to the functionality which is beneficial if one wants to make the ankle audiometer a commercial product.

6
Conclusion

In summary, it is shown in this project that it is possible to build an ankle audiometer with only analogue electronics that performs well compared to the standards and requirements that it has to comply with. The final prototype does not only produce highly stable results but also complies with all requirements from Section 1.7.

The next step in the development of the device is to perform a pilot study to verify that the device is safe to use on patients and to do a series of bench tests that ensures that the device complies with all the mentioned standards. Although the device is designed to comply with some standards, harmonised with the MDR, which is necessary to license it as a medical device. It is only proven to be in accordance with EN 60645-3:2007 which dictates maximum THD for bone vibrators.

6.1 Future work

There are several possibilities for expanding the final product and for improving upon the work already done. The following points are the most important areas of further study.

- Construct a patient attachment solution which ensures constant and repeatable measurements.
- Perform studies that verify the functionality of the device.
- Verify if pure tone audiometry is comparable to warbled tone audiometry.
- Implement a solution for stimulating at different frequencies to enable diagnosis of different vestibular disorders.

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