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Mass-deployable Objective Hearing Screening with Otoacoustic Emissions

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Abstract

Hearing loss is one of the most widespread disabilities worldwide. However, it can often be addressed by early detection and intervention. Untreated hearing impairments are still prevalent, especially in rural areas of developing countries. Children in such areas have a high risk for hearing loss caused by malnutrition and inadequate medical facilities. In addition, many adults in urban areas are continuously exposed to high noise levels in their work environments like factories or construction sites. Still, there is a lack of regular hearing screenings. This is mainly caused by the high prices of screening and testing equipment, which limit their availability. Further, such equipment is currently designed to be used by specialists only, which are often unavailable. Hence, hearing loss often remains undetected and cannot be treated in time. As a result, there is a strong interest in providing comprehensive hearing screening. In this thesis, techniques are presented to build mass-deployable low-cost hearing screening solutions based on otoacoustic emissions (OAEs), which are to be used by laypersons. The goal is to develop objective hearing screening devices, which can be used in the same way as clinical thermometers and blood pressure monitors are being used today.

Simple hearing screening tests require some form of cooperation and feedback from the patient. For example, the patient presses a button when a sound can be heard. These subjective hearing screening tests, however, are unsuitable in many situations, e.g. when screening neonates or small children. For this reason, objective hearing screening tests have been devised, where no active feedback of the patient is required. The measurement of OAEs, which are sound emissions of active processes in the cochlea, is a common procedure to assess the function of the peripheral hearing. Its main advantages are that only a single acoustical probe needs to be inserted into the ear canal and the short measurement duration. Existing OAE measurement systems consist of two major parts: First, an ear probe that is inserted into the ear canal during the measurement. This ear probe consists of several transducers, i.e. microphones and speakers. Second, the measurement device, which is connected to the ear probe by a cable. The measurement device drives the speakers and analyses the recorded response from the microphone. At the same time, the measurement device provides the user interface to control the measurement and display the results. The approaches discussed in this thesis focus on using commercial of the shelf (COTS) hardware components and incorporation of established platforms, such as smartphones, which are ubiquitous around the world. Other cost optimizations can be achieved by lowering the number of components needed and reducing the complexity of manufacturing process. We not only present newly developed OAE screening devices but also introduce a novel design for an ear probe.

In this thesis, we first analyze, how a smartphone can be integrated into such an OAE-based hearing screening system. Based on the results, we first propose a low-cost standalone hearing screening system. Its novel architecture merges the OAE ear probe into the body of the measurement device. To improve the usability, we extend this system with additional external sensors to assess the probe placement in the ear canal. The data of the additional sensors is then used to detect in which side, left or right, the OAE measurement was taken. The resulting cable-less system is intended to be used in a style similar to a clinical infrared in-ear thermometer.

In contrast to the low-cost standalone hearing screening system, we also introduce a smartphone-based objective hearing screening system. For *subjective* hearing screening systems, smartphones have already been used in the past. The advantages of integrating smartphones are their ubiquity, easy to use interface and connectivity. These properties enable new possibilities for low-cost hearing screening, such as telemedicine. In the presented approach, we use the existing audio subsystem of Android smartphones to directly connect to an existing off-the-shelf OAE ear probe with only minimal external hardware. At the same time, we only use the standard Android application programming interface (API). The main advantage of this approach is that the user only needs to download the corresponding app and connect the OAE ear probe to the headphone jack. As the audio subsystem of smartphones is not designed to measure OAEs, we developed a complete setup to measure OAEs and circumvent the limitations of the underlying hardware and software. However, a detailed characterization and OAE measurements analysis showed that only a fraction of smartphone models is suitable for hearing screening. The suitable smartphones models showed promising results and can be used to reliably perform OAE hearing screening tests.

Having discussed two innovative approaches, which mostly focus on the measurement device of an OAE hearing screening system, this thesis also discusses a novel architecture for the OAE ear probe itself. To simultaneously emit a stimulus into the ear canal and record the response, OAE ear probes consist of microphones and speakers. We propose a simplified low-cost ear probe architecture to measure transient evoked OAEs (TEOAEs). This novel ear probe architecture consists of only one speaker, which is used to emit the transient click stimulus. The same speaker is then used to record the response. This design drastically reduces the complexity and cost of the ear probes and, at the same time, makes them more robust during use. Five different prototype probes with different transducer types were built and characterized. Two of these probes were selected and their feasibility demonstrated in a small study.

All techniques that were discussed and reviewed in this thesis are based on existing and established OAE measurement procedures. This allows the comparison to existing literature and available measurement systems. We have shown that it is not only possible to build low-cost objective hearing screening devices that can be used by laypersons, but that these devices are also comparable to expensive devices available on the market. We believe that the new approaches presented in this thesis can greatly improve the accessibility and coverage of objective hearing screening, especially in low and middle-income countries.

Zusammenfassung

Hörverlust ist eine der am weitesten verbreiteten Behinderungen weltweit. Allerdings kann in vielen Fällen einem Hörverlust durch rechtzeitiges Erkennen und Intervenieren begegnet werden. Unbehandelter Hörverlust ist dennoch verbreitet, insbesondere in ländlichen Gebieten von Entwicklungsländern. Dort sind Kinder einem erhöhten Risiko ausgesetzt, welches durch Mangelernährung und ungenügende medizinische Versorgung verursacht wird. Zusätzlich sind viele Erwachsene in ihrem Arbeitsumfeld dauerhaft hohen Lärmpegeln ausgesetzt, wie etwa in Fabriken oder im Straßenverkehr. Dennoch werden regelmäßige Hörscreenings nicht flächendeckend durchgeführt. Die Hauptursache dafür sind die hohen Kosten für Hörscreening-Systeme. Zusätzlich sind diese Systeme zur Benutzung durch Spezialisten entworfen, die häufig ebenfalls nicht verfügbar sind. Daraus folgt, dass Gehörverlust häufig nicht erkannt wird und nicht mehr rechtzeitig behandelt werden kann. Daraus ergibt sich ein großes Interesse an Technologien für flächendeckende Hörscreening-Lösungen. In dieser Arbeit werden auf otoakustischen Emissionen (OAEs) basierende Techniken vorgestellt, die massentaugliche und kostengünstige Hörscreening-Geräte ermöglichen, welche von Laien benutzt werden können. Das Ziel ist die Entwicklung von objektiven Hörscreening-Geräten, die so einfach genutzt werden können wie ein Fieberthermometer oder ein Blutdruckmessgerät.

Einfache Hörscreening-Tests erfordern das Mitwirken des Patienten, zum Beispiel das Drücken einer Taste, wenn ein Ton gehört wird. Diese subjektiven Hörscreening-Tests sind aber in vielen Situationen ungeeignet, zum Beispiel beim Testen von Neugeborenen und Kleinkindern. Aus diesem Grund wurden objektive Hörscreening-Tests entwickelt, bei denen kein aktives Mitwirken mehr erforderlich ist. Die Messung von OAEs, welche Schallemissionen von aktiven Prozessen des Innenohrs sind, ist ein verbreitetes Verfahren. Die Hauptvorteile sind die kurze Messdauer und dass nur eine akustische Ohrsonde im Gehörgang platziert werden muss. Typische OAE-Messgeräte bestehen aus zwei Hauptkomponenten: Erstens, einer Ohrsonde die während des Messvorgangs Gehörgang platziert wird. Diese Ohrsonde besteht aus mehreren Mikrofonen und Lautsprechern. Zweitens, einem Messgerät, welches mit der Ohrsonde verbunden ist. Das Messgerät steuert die Lautsprecher an und analysiert das aufgezeichnete Signal des Mikrofons. Gleichzeitig stellt das Messgerät die Benutzerschnittstelle bereit, mit der die Messung gesteuert wird und die Ergebnisse angezeigt werden. Die Herangehensweisen, die in dieser Arbeit diskutiert werden, fokussieren sich auf die Benutzung von handelsüblichen Hardware-Komponenten und die Integration von verbreiteten Plattformen, wie etwa Smartphones, die weltweit verfügbar sind. Es werden nicht nur neue Ansätze für OAE-Hörscreening-Geräte vorgestellt, sondern auch neuartige Entwürfe für Ohrsonden.

In dieser Arbeit wird zunächst analysiert, wie ein Smartphone in ein OAE-basiertes Hörscreening-Gerät integriert werden kann. Basierend auf diesen Ergebnissen wird ein kostengünstiges, eigenständiges Hörscreening-System vorgestellt, dessen neuartige Architektur die OAE-Ohrsonde mit dem OAE-Messgerät in einem Gehäuse zusammenführt. Um die Bedienbarkeit zu verbessern, erweitern wir dieses System um zusätzliche externe Sensoren, welche die Sondenplatzierung im Gehörgang überwachen. Die aufgezeichneten Daten dieser Sensoren werden anschließend ausgewertet, um zu bestimmen, ob die OAE-Messung im linken oder rechten Ohr ausgeführt wurde. Das Ergebnis ist ein Messsystem ohne Ohrsondenkabel, das ähnlich benutzt werden kann wie ein Infrarot Ohr-Thermometer.

Als Gegensatz zu dem eigenständigen OAE-Messgerät wird auch ein Smartphone-basiertes, objektives Hörscreening-System vorgestellt. Smartphones wurden bereits in der Vergangenheit für *subjektive* Hörtests verwendet. Die Vorteile dieses Ansatzes sind die weite Verbreitung, die intuitive Bedienbarkeit und Konnektivität, die ein Smartphone mit sich bringt. In diesem Ansatz benutzen wir das vorhandene Audio-Subsystem von Android Smartphones, um eine handelsübliche OAE-Ohrsonde anzusteuern, und das mit nur wenigen externen Bauteilen. Gleichzeitig nutzen wir ausschließlich die Programmierschnittstelle (API) von Android. Der Hauptvorteil dieses Ansatzes ist, dass der Benutzer lediglich eine App installieren und die OAE-Ohrsonde mit dem Kopfhöreranschluss verbinden muss. Allerdings ist das Audio-Subsystem ist nicht für die Messung von OAEs ausgelegt. Deswegen wurde ein System entwickelt, das es erlaubt, OAEs zu messen und gleichzeitig die Limitierungen der zugrunde liegenden Hard- und Software zu umgehen. Jedoch zeigte eine detaillierte Charakterisierung und OAE-Messungen, dass nur ein Bruchteil der untersuchten Smartphone-Modelle für OAE-Hörscreenings geeignet ist. Die verbliebenden Modelle hingegen zeigten vielversprechende Ergebnisse und könnten genutzt werden, um zuverlässig OAE-Hörtests durchzuführen.

Die bereits vorgestellten Ansätze befassen sich hauptsächlich mit dem Messgerät-Teil eines OAE-Hörtest-Systems. Diese Arbeit behandelt aber auch eine neuartige Architektur für die Ohrsonde. Um gleichzeitig einen Reiz im Gehörgang erzeugen zu können und die Reaktion aufzuzeichnen, besteht eine OAE-Ohrsonde aus Mikrofonen und Lautsprechern. Wir präsentieren eine vereinfachte, kostenreduzierte Ohrsonden-Architektur, um transient evozierte OAEs (TEOAEs) zu messen. Diese neuartige Ohrsonden-Architektur besteht aus einem einzigen Lautsprecher, der einen transienten Klick-Reiz erzeugt. Der gleiche Lautsprecher wird genutzt, um die Antwort aufzuzeichnen. Diese Architektur reduziert die Komplexität und die Kosten der Ohrsonde drastisch und macht sie gleichzeitig robuster in der Anwendung. Fünf unterschiedliche Ohrsonden-Prototypen mit unterschiedlichen Lautsprechern wurden vorbereitet und charakterisiert. Davon wurden zwei ausgewählt und in einer kleinen Studie erfolgreich evaluiert.

Alle in dieser Arbeit vorgestellten Techniken basieren auf schon existierenden und etablierten OAE-Prozeduren. Dies ermöglicht den Vergleich mit der existierenden Literatur und bereits verfügbaren Messystemen. Wir haben gezeigt, dass es nicht nur möglich ist, kosteneffiziente objektive Hörscreening-Systeme zu konstruieren, die von Laien genutzt werden können, sondern dass diese Systeme auch mit höherpreisigen, bereits am Markt verfügbaren Systemen vergleichbar sind. Wir glauben, dass die hier vorgestellten Herangehensweisen dazu geeignet sind, die Abdeckung von und den Zugang zu objektiven Hörtests zu verbessern, insbesondere in Ländern mit niedrigen und mittleren Einkommen.

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1 Introduction

Hearing is the sense of acoustic perception. This sense is fundamentally connected to personal communication, well-being, education and economic success as it enables the interaction between individuals within a society. However, it is estimated, that 1.5 billion people suffer from some form of hearing loss. Of those, around 430 million experience hearing loss to such a degree that their everyday life is affected [182].

Hearing loss impacts the psychosocial well-being and the quality of life [126]. Over the course of a life, starting from neonates and small children, it affects many personal areas, including language development, achieved level of education and economic independence [102], [145]. Fortunately, up to $60\,\%$ of the causes of hearing loss in children can be prevented [180]. These preventable causes include common ear diseases, ear infections (otitis media) and vaccine-preventable illnesses. Some of these causes can be minimized by appropriate ear hygiene [179], avoiding nutritional deficiencies [42] and breastfeeding [18]. Other manageable risks persist during the full life-span, e.g. exposure to chemicals (related to occupation or certain medicines) and exposure to increased noise levels over extended periods of time [167]. Noisy environments for the latter include traffic, factory work and recreational settings, e.g. music. This leads to noise-induced hearing loss (NIHL). However, other causes for hearing loss cannot be avoided directly. Approximately $50\,\%$ of hearing loss in neonates can be attributed to genetic factors [157]. Nonetheless, the majority of hearing loss in the general population is attributed to age-related hearing los (ARHL) [72]. Since damage to the auditory system is often permanent and culminating over the course of life, ARHL is linked to NIHL and other causes [104].

Interventions are available and effective for many causes of hearing loss, either by restoring the original hearing capacity or by mitigating the impact of hearing loss. The success of these interventions is made possible by improvements in the fields of hearing technology, diagnostics and medicine. For many cases of conductive hearing loss (CHL), which is caused by diseases in the outer and middle ear, e.g. otitis media, medical and surgical interventions exist [111]. If the hearing loss is permanent and cannot be reverted, other hearing rehabilitation measures can be chosen. Hearing rehabilitation with hearing technology improves quality of life for all types of hearing loss [22]. These hearing technologies include hearing aids and cochlear implants. Hearing aids are an effective option to treat mild to moderate cases of hearing loss [29], where they can be used in a non-invasive, low-risk manner. These devices amplify the sound which reaches the tympanic membrane. More recent is the development of implantable hearing aids, which replace some functions of the peripheral hearing, e.g. the middle ear [15]. Cochlear implants take over the complete function of the peripheral hearing and are connected to the auditory nerve. These devices have become indispensable for the treatment of many cases of profound or total hearing loss, especially those with causes related to the inner ear [22], [138]. All interventions, including those based on medical and hearing technology, should include rehabilitative therapy [46], [53].

The effectiveness of the interventions and the prevention of negative impacts of hearing loss is dependent on the early identification of hearing loss. For small children, early treatment of hearing loss is the prerequisite for the development of communication skills and language acquisition [186]. Unidentified hearing loss can have a permanent impact on cognition [27] and is a risk factor for age-related dementia [117]. In any case, affected persons will benefit from early detection and management of hearing loss.

Depending on the underlying disease, hearing loss may manifest itself at differing degrees of severity. A common reference for the degree of hearing loss is the pure tone audiometry (PTA) [68]. In this procedure, the threshold of hearing for a single pure tone is measured. This threshold is set in relation to a baseline hearing threshold, which results in the hearing level (HL), commonly specified in dB. For the classification of hearing loss, the hearing level at frequencies of 0.5, 1, 2 and $4\,\mathrm{kHz}$ is averaged. For purposes of identifying hearing loss that requires interventions, a resulting averaged hearing level of $40\,\mathrm{dB}$ in the better hearing ear is used as a threshold [35], [44]. The threshold for children is set more stringent at $30\,\mathrm{dB}$ in the better hearing ear. Hearing screening tests are designed to identify individuals that suffer from hearing loss beyond the threshold. However, it should be noted that even with “mild” hearing loss, which is defined at a HL of $20\,\mathrm{dB}$ to $35\,\mathrm{dB}$, treatment might be necessary [108].

1.1 Hearing Screening

Hearing screening is often the first step to identify hearing loss. Hearing screening tests are designed to quickly evaluate the hearing capability of a person. The goal of such a test is to discern people with hearing loss from those with normal hearing. These tests do not intent to reveal underlying causes of hearing loss or even the quantitative degree of hearing loss. For that reason, the result of such hearing screening tests is either “pass” or “refer”. A “pass” result indicates that the hearing is normal, within the specific uncertainty of the used test. In contrast, a “refer” indicates that the patient should seek care of a medical professional. However, a “refer” result does not necessarily imply hearing loss. Reasons for such a result might also include adverse test conditions, e.g. high ambient noise levels or some cases of temporary hearing loss, e.g. due to liquid in the tympanic cavity. If the hearing screening results in a “refer”, care of a medical professional should be sought, who will perform a comprehensive audiological evaluation. These diagnostic procedures aim to identify the underlying diseases and quantify the severity of hearing loss. Further, the treatment, observation and rehabilitation are decided. The quality of hearing screening tests is gauged by their sensitivity and specificity [5]. Sensitivity is the proportion of those patients with actual hearing loss (positive condition) that are correctly identified by the test, i.e. the test resulted in “refer”. Specificity is the proportion of those patients with normal hearing (negative condition) that are correctly identified by the test, i.e. the test resulted in “pass”.

Hearing screening tests can additionally be divided into subjective and objective tests. Subjective tests require the cooperation of the patient. These tests usually involve the press of a button or signaling by hand if a certain sound can be heard, e.g. PTA. Other such tests require the patient to comprehend speech at elevated noise levels and to reply which words were understood. In contrast, objective hearing screening tests do not require active cooperation of the patient. These objective procedures are indispensable when testing neonates and small children. All objective tests have in common that an involuntary physiological response is measured. Suitable objective test procedures for hearing screening include the measurement of otoacoustic emission (OAE) and auditory brainstem response (ABR) [69]. OAEs are measured by stimulating active processes in the inner ear, from which sound travels backwards to the ear canal. There, a microphone can detect the minuscule signal if the hearing is normal. The measurement of ABR is done by stimulating the hearing and recording electrical activity with electrodes on the scalp. The main difference is that ABR needs the placement of scalp electrodes, while for OAE only an ear probe is necessary. Screening time for two ears is up to ten minutes with ABR versus two minutes for OAE [69]. However, OAE fails to detect many cases of auditory neuropathy (AN), which are disorders associated with the inner hair cells up to the auditory nerve.

As already discussed, the early detection of hearing loss is an important factor for the success of treatment and rehabilitation. Hearing screening, with either objective or subjective tests, can hence be used as a tool in different circumstances to aid the identification of hearing loss. Each circumstance might have varying requirements for the hearing screening method used, which leads to differing solutions in each situation. In the following, three common applications of hearing screening are discussed.

Neonatal Hearing Screening

The prevalence of hearing loss is between one and three per 1000 live birth in a well baby nursery [44]. Early identification and intervention is exceptionally important for children. Hearing loss leads to sensory deprivation during crucial early periods of neurologic and cognitive development. Without screening, the impairment can remain undetected for two to seven years [69]. Detection of hearing loss and appropriate intervention before the age of six months leads to significantly better language development in children, compared to those where detection and intervention is identified after the age of six months [186].

Neonatal hearing screening can follow one of following strategies: opportunistic, at-risk and universal. The opportunistic strategy only screens children for whom hearing loss is suspected, e.g. by the parents. This approach often results in late detection. All neonates with increased risk factors are screened with the at-risk strategy. However, only about $50\,\%$ to $60\,\%$

of infants with hearing loss have known risk factors [69], which leads to late detection in a significant share of cases. The universal strategy aims to screen all neonates for hearing loss. Universal hearing screening has shown clear benefits in the development of children, compared to the other screening strategies [172]. This has led to the implementation of universal neonatal hearing screening (UNHS) programs around the globe based on the measurement of OAE and ABR [183]. Hearing screening should take place ideally before discharge from the birthing center or no later than one month of age. The goal is to detect all infants with significant bilateral hearing loss of more than $35\,\mathrm{dB}$ in the better hearing ear before the age of three months and intervention before the age of six months [44], [74]. For the general neonate population, screening with OAEs is appropriate, however, if certain risk-factors are involved, the prevalence of AN increases. When these risk factors are present, for example, if a newborn is admitted to a neonatal intensive care unit (NICU), hearing screening should be based on ABR [106], [155]. To lower refer rates, UNHS can also consist of multiple stages, where the first screening is OAE-based. On refer, the second stage could then be ABR-based [67].

As important as the hearing screening itself is the follow-up audiologic evaluation. Lost-on-follow-up rates of up to $65\,\%$ have been reported [129]. To improve the benefits of early detection, UNHS programs are often embedded into overarching early hearing detection and intervention (EHDI) programs [137].

Hearing Screening in Pre-School and School

Screening in schools offers an additional opportunity to detect hearing loss, since most children will attend school [40]. The implementation of UNHS programs has been deemed useful to identify congenital hearing loss. However, children who suffered from mild hearing loss at birth or experience progressive hearing losses might remain untreated. Additionally, hearing loss developed later in life, e.g. caused by recurrent middle ear diseases, remains hidden. To identify these cases, school-based hearing screening programs have been established [185].

Hearing screening in schools is usually based on subjective audiometry tests. OAEs can be used as objective tests, especially in pre-schools and for children for whom PTA is not developmentally appropriate [6]. However, regardless of the used procedure, lack of awareness and trained specialists, as well as high cost of equipment limits the availability, especially in low-resource settings.

Hearing Screening of Adults

Hearing screening of adults can be targeted to reveal hearing loss from different causes. First, due to the aging global population, age-related hearing los (ARHL) will become more prevalent in the future [178]. In extreme cases, this can lead to increasing encapsulation and isolation of a person. Early detection and intervention with hearing aids can significantly improve the quality of life [181]. Additionally, untreated hearing loss appears to be a strong risk factor for dementia in older adults [117]. Second, it is important to identify hearing loss caused by either environmental noise exposures or the exposure to ototoxic chemicals, e.g. certain medicines. Here, persons who belong to high-risk groups should be screened regularly.

Adult hearing screening is currently limited by unawareness and social stigma of hearing loss, combined with limited access to audiological evaluations. These reasons lead to a gap of several years between the actual occurrence of the hearing loss and the seeking for help [154].

1.2 Mass-deployable Objective Hearing Screening

The need for early hearing detection and intervention (EHDI) programs has been recognized in most countries around the world. Especially detection of congenital hearing loss with UNHS has been a success for personal well being of the affected. In addition, the costs of the programs, e.g. cost of conducting the screening and referring false positives, are regularly outweighed by their economic benefits since early intervention is more cost effective and fewer rehabilitative measures are necessary. An overall economic gain can be achieved even in low and middle-income countries (LMICs), such as India [24], [149]. However, only 33 % of global population lives in areas, where UNHS coverage is almost complete, i.e. more than 85 % of all newborns are screened. Another 38 % of the global population lives in areas, where newborn hearing screening is virtually non-existing as less than 1 % of all neonates are screened. While there are exceptions, the gross domestic product (GDP) per capita correlates with hearing screening coverage. The GDP per capita in areas with full coverage is approximately ten times higher compared to those areas without coverage [124].

Access to hearing care services is often limited due to insufficient infrastructure and required equipment, especially in low-resource settings [119], [171]. Additional difficulties are faced by those living in rural areas, since access to health care requires extended travels [20], [166]. Another limitation is the availability of trained experts. In the majority of African countries, only a single ear, nose, and throat (ENT) specialist and audiologist is available per million people. In comparison, most European countries have up to 50 times higher densities [76]. To improve early detection and treatment of hearing loss, efforts have been made to redistribute tasks that are typically performed by ear and hearing care specialists to other non-specialists. This task-sharing aims to make better use of the available human resources at the cost of shorter training and fewer qualifications of those involved. Basic tasks and hearing screening can be performed by health workers, nurses or general practitioners [162].

In summary, reasons for limited coverage with hearing screening are high cost of the equipment, lack of access to appropriate facilities and lack of specialists with the necessary training. To improve the coverage of hearing screening, the access barriers to hearing screening devices as well as to their usage must be lowered. Low-cost subjective, i.e. based on voluntary patient feedback, hearing screening by health workers and laypersons is already available, e.g. by using smartphones [21], [134]. This thesis is focused on objective hearing screening, which allows conducting hearing tests without active participation of the patient. The goal of this thesis is to provide steps towards mass-deployable objective hearing screening technology. We aim to lower the overall cost of manufacture and of operation of such devices. Further, we want to enable untrained healthcare workers and laypersons to conduct the screening. Cost reductions shall be achieved by re-engineering existing objective hearing screening technology, to be based on low-cost consumer grade component or existing platforms such as smartphones.

The work in this thesis is based on OAEs, which can be measured in a non-invasive manner with just an ear probe. All techniques presented in this work are based on established measurement procedures such as distortion product OAE (DPOAE) and transient evoked OAE (TEOAE), which leads to a high quality of screening as well as comparable results.

1.3 Key Contributions

The benefits of comprehensive hearing screening are well understood. However, large gaps remain in the hearing screening coverage world-wide, especially in low and middle-income countries. The focus of this thesis is the investigation of objective hearing screening technologies, which aim to close this gap. Three broad areas in which hearing screening technology could be improved to further help the adoption of objective hearing screening were identified:

Cost Reduction of Objective Hearing Screening Technology

- We propose and evaluate novel system architectures, in which the overall number of components is lowered.
- We systematically investigate the benefits of computational offloading for OAE-based hearing screening.
- A low-cost standalone system is presented, which integrates the OAE ear probe into the device body, thus eliminating the cable, which reduces cost, production expenditure and improves reliability.
- We present a novel smartphone-based objective hearing screening system, which needs only few additional external components.
- We also present a simplified OAE ear-probe, which uses one transducer for both stimuli generation and recording of OAEs.
- The proposed system architectures and ear probes are based on consumer electronic components, which are commercial of the shelf (COTS).

Improved Usability of OAE-based Hearing Screening for Laypersons

- We equipped an OAE ear probe with additional sensors with the goal to aid the examiner with probe placement.
- Based on the data of the additional sensors, we present a system to detect the ear, i.e. left or right, which is currently measured.
- We present smartphone-based OAE hearing screening systems, which allow the examiner to interact with familiar and matured user interfaces.
- We propose a single speaker ear probe that is more robust against blockage. This probe could potentially be offered as single-use part, which would simplify the probe tip.

Connectivity and Telemedicine in the Context of Mass-deployable Hearing Screening

- The ubiquitous smartphones are integrated in our proposed architectures. This allows for proper integration of the smartphones with online services, such as management of follow-up examinations and telemedicine.
- The presented smartphone-based systems offer high advantages in remote trouble shooting and device management, e.g. for service and calibration.

1.4 Organization and Reading Sequence

This thesis is structured into six chapters. In this first chapter, the global state of hearing loss was introduced. Further, the need for low-cost, accessible and easy to use OAE-based hearing screening, especially in low and middle-income countries, was highlighted. More details on the origin of OAEs and the underlying procedures are provided in Chapter 2, which serves as a common reference for the following main chapters. The remainder of this thesis consists of three mostly self contained main chapters (3, 4, 5), which can be read independently. The reader is encouraged to start with the main chapters and reference Chapter 2 for more details as needed. The chapters are outlined below:

Chapter 2 provides the background for OAE-based objective hearing screening. The used notation for levels and their relation to sound pressure and other physical units are briefly introduced. This is followed by an introduction to the auditory system of humans. The focus lies on the peripheral part of the ear, which includes most of the structures responsible for the generation of OAEs. A special emphasis is put on how each structure in the auditory system plays a role in the physiological generation of OAEs, as well as how they interact during the measurement. The next section is dedicated to the most prominent OAE measurement protocols, which are grouped by the stimulus that is used to excite the OAE response. This section describes how the OAEs in these protocols are stimulated and how the inner ear reacts to this excitation with a characteristic OAE response.

The remainder of Chapter 2 describes the measurement of OAEs from a technical and instrumentation point of view. A generic measurement system is presented and the necessary subsystems highlighted. Additionally, the input and output path from acoustic over electronic to digital domain is discussed, which is followed by a description of the digital signal processing during OAE measurement. The buffer-based processing approach and the relevant processing steps are presented. A procedure for the absolute calibration of sound pressure readings of OAE probes is shown next. Based on this calibration, the in-ear calibration (IEC) procedure used in this thesis is presented, which is necessary to correctly set the sound pressure of the stimulus. Alternative IEC procedures are discussed as well. A brief overview of the IEC-based verification of ear probe placement is given next. Since noise is a major influence in the performance of OAE-based measurements, noise and noise reduction in the context of OAE measurements are discussed, as well as how noise can be reduced with the help of additional acoustic transducers. This chapter concludes with a discussion on the practical measurements of TEOAE and DPOAE in a hearing screening context.

Chapter 3 investigates the design of a low-cost standalone hearing screening device. In this novel approach, the ear probe is not connected with a cable to the measurement device, but the ear probe body is merged into the enclosure of the measurement device, which is held and operated similar to an infrared fever thermometer. The chapter discusses the need and possible use case scenarios of such a device. The device design was considered in conjunction with a connected smartphone. For that reasons, computational offloading to a smartphone and the most beneficial partitioning of the algorithms is evaluated. Based on the results of this evaluation, the standalone architecture was chosen, where a smartphone remains optional, e.g. for patient data entry, with a near field communication (NFC)-based communication. The resulting hardware design and prototypes, including printed circuit boards (PCBs) and a 3D-printed enclosure, are presented. The extensible firmware, based on a real-time operating system (RTOS), is discussed, which is designed such that the device can be easily modified to be used in related experiments, is shown as well.

The extensible nature of the device platform is utilized in the experiments in the remainder of Chapter 3: the standalone device was equipped with additional low-cost sensors, which acquire data during the ear probe insertion. The idea in this novel approach is to provide feedback to the examiner during the whole OAE measurement procedure, to aid with probe placement and to improve the success rates of the hearing screening. The sensors on the ear probe consist of four copper electrodes, of which the capacitance is evaluated, and two distance sensors. Additionally, an inertial measurement unit (IMU), with acceleration and turn rate data, is placed on the main PCB. A study was conducted, where the resulting data was collected during the insertion and the actual OAE measurement. The data was then subsequently analyzed to automatically classify in which ear, left or right, the probe was inserted. This might prove useful to aid the layperson examiner with data entry and automatic documentation of the results. The work presented in this chapter was part of the Indo-German research project Sound4All and the discussion has partly appeared in [62].

Chapter 4 is dedicated to the opposite of the previous chapter. The basic strategy was to integrate as much of the OAE measurement system as possible into a smartphone. In this unique approach, the headphone jack of Android smartphones is used to interface an existing OAE ear probe with only a few passive external electronic components. However, the audio subsystem of these phones is neither designed nor suited for OAE measurements. Initially, a set of smartphones is characterized on their audio capabilities in terms of reproducible in-/outputs, linearity and time response. Methods to work around the specific limitations are devised and a full OAE-based hearing screening system set up, with TEOAE and DPOAE capabilities. The chapter is concluded with a trial, in which OAEs in normally hearing adults were measured with the smartphones, as well as with a commercially available OAE measurement system for comparison. The work in this chapter was previously published in [64].

Chapter 5 focuses, in distinction to the previous chapters, on the OAE ear probe. OAE ear probes usually consist of multiple acoustic transducers, at least one speaker and one microphone. In this chapter, an OAE ear probe is proposed that only consists of a single loudspeaker. The probes are designed to measure TEOAEs, during which the speaker is first used to emit the transient stimulus and subsequently is used as a microphone. This novel approach reduces the cost and complexity of the probe. At the same time, it is more robust against blockage due to the increased probe tip channel diameter, which now only needs a single acoustic channel. Ear probes based on five different transducers are designed and built as 3D-printed prototypes. Each probe is then characterized in an ear simulator and in a custom calibration cavity. Two of the probes showed promising behavior. A circuitry to simultaneously drive and record from the speaker was set up. A small TEOAE-based trial was performed and the results evaluated. The work in this chapter was previously published in [61] and [63].

The thesis in concluded in Chapter 6. The contributions of the previous chapters are compared to each other and existing OAE-based hearing screening solutions. A discussion of the possible use cases in the context of mass-deployable hearing screening is presented.

1.5 List of Publications

This thesis is partly based on work, which was previously published. The following publication form the basis of the thesis:

- N. Heitmann, P. Kindt, T. Rosner, *et al.*, "Sound4All: Towards affordable large-scale hearing screening", in *12th International Conference on Design & Technology of Integrated Systems In Nanoscale Era (DTIS)*, Palma de Mallorca, Spain: IEEE, Apr. 2017
- N. Heitmann, T. Rosner, and S. Chakraborty, "Designing a Single Speaker-based Ultra Low-Cost Otoacoustic Emission Hearing Screening Probe", in *Global Humanitarian Technology Conference (GHTC)*, Seattle, WA, USA: IEEE, Oct. 2020
- N. Heitmann, P. Kindt, and S. Chakraborty, "Late Breaking Results: Can You Hear Me? Towards an Ultra Low-Cost Hearing Screening Device", in *57th Design Automation Conference (DAC)*, San Francisco, CA, USA: ACM, Jul. 2020
- N. Heitmann, T. Rosner, and S. Chakraborty, "Mass-deployable Smartphone-based Objective Hearing Screening with Otoacoustic Emissions", in *23rd International Conference on Multimodal Interaction (ICMI)*, Montréal QC Canada: ACM, Oct. 2021

2 Background

This chapter introduces the basic background for objective hearing screening with otoacoustic emissions (OAEs). First, the notation of levels used in this thesis is given. This is followed by a brief description of sound pressure as well as examples of sound pressures which are intended to be used as reference for ambient noise in the remainder of this work. Section 2.2 introduces the peripheral human auditory system. A special emphasis is put on how OAEs are generated and can be measured in the human ear. While OAEs are generated under various circumstances, certain excitation procedures are more common. Section 2.3 is dedicated to these procedures and the underlying mechanics of how OAEs are generated with each excitation. Finally, Section 2.4 is dedicated to the instrumentation, evaluation and measurement of OAEs.

2.1 Physical Quantities and Units

2.1.1 Levels

In acoustic and electronic sciences, *power quantities*, sometimes also referred to as *quadratic* quantities, are physical quantities that are linear to a power. Examples are energy and sound intensity. Other physical quantities can be described as *root-power quantities*, sometimes referred to as *field quantities*, of which the square is typically proportional to a power in a linear system. Examples are voltage, electric current, sound pressure.

It is often helpful to describe the behavior of a system with ratios, e.g. the output voltage of an amplifier dependent on its input voltage. However, in the field of acoustic measurements, the wide dynamic range from potentially nanovolts to kilovolts is needed. Hence, the usage of decibel (dB), a logarithmic measure, is very common:

$$L_P = 10\ \log_{10}\left(\frac{P_1}{P_0}\right)\,\mathrm{dB} \tag{2.1}$$

$$L_F = 10\ \log_{10}\left(\frac{F_1^2}{F_0^2}\right)\,\mathrm{dB} = 20\ \log_{10}\left(\frac{F_1}{F_0}\right)\,\mathrm{dB} \tag{2.2}$$

$$\begin{aligned} L_P &: \text{power level} \\ L_F &: \text{field level} \\ P_0, P_1 &: \text{power quanitities} \\ F_0, F_1 &: \text{root-power quanitities} \end{aligned}$$

To account for power quantities and root-power quantities, the latter are squared. This is done to correctly represent changes in amplitude of either related quantities, such that the decibel values change by the same amount. A $10\,\mathrm{dB}$ change of a power quantity corresponds to a increase of factor 10, while a change of $20\,\mathrm{dB}$ for a root-power quantity also results in a factor of 10.

These ratios can also be calculated with a constant P_0 or F_0 as a reference, in which case they are referred to as *levels*. Levels are ratios referenced to a fixed quantity. For example, a voltage $F_0 = 1\,\mathrm{V}$ and $F_1 = 25\,\mathrm{mV}$ results in $L = -32\,\mathrm{dB}$. To indicate the reference dimension and value (in this example a voltage of $U = 1\,\mathrm{V}$), the following notations are preferred [70]:

$$L_U(re\ 1\,\mathrm{V}) = -32\,\mathrm{dB} \quad \text{or} \quad L_{U/1\,\mathrm{V}} = -32\,\mathrm{dB}$$

However, in acoustics and some other areas, it is common to denote the reference quantity as a suffix to the decibel unit symbol:

$$L_U = -32\,\mathrm{dB\,V}$$

This notation must not be understood as a multiplication of the decibel value and unit with the unit volt, but indicates that the reference F_0 is $1\,\mathrm{V}$. Both notations have in common that the resulting level does not have a physical dimension. However, if the reference value and dimension are given, the initial P_1 and F_1 can of course be calculated.

2.1.2 Sound

Sound Pressure

Sounds can be described as mechanical waves propagating through a transmission medium like gas, liquid or a solid. The most familiar form of sound is using air as a transmission medium. Sound is the time-varying sound pressure $p(t)$. The unit of sound pressure is Pascal (Pa):

$$1\,\mathrm{Pascal} = 1\,\mathrm{Pa} = 1\,\frac{\mathrm{N}}{\mathrm{m}^2} = 1\,\frac{\mathrm{kg\,s}^2}{\mathrm{m}} \tag{2.3}$$

Slow changes in air pressure with frequencies between $1\,\mathrm{Hz}$ and up to $16\,\mathrm{Hz}$ are called infra sound, as it lies below the range of human hearing. Fast changes above $20\,\mathrm{kHz}$ are called

Table 2.1: Sound pressures with their corresponding levels and examples for ambient sound pressures [116].

Sound pressure p (Pa)	Sound pressure level $L_{(p/20\,\mu\mathrm{Pa})}$ (dB)	$L_{(p/\mathrm{Pa})}$ (dB)	Example
$2 \cdot 10^{-6}$	-20	-114	Brownian noise of ambient air [50], [59]
$2 \cdot 10^{-5}$	0	-94	Hearing threshold
$2 \cdot 10^{-4}$	20	-74	Forest with calm wind
$2 \cdot 10^{-3}$	40	-54	Library
$2 \cdot 10^{-2}$	60	-34	Office
$2 \cdot 10^{-1}$	80	-14	Busy city road
1	94	0	
2	100	6	Jackhammer, siren
$2 \cdot 10^{1}$	120	26	Jet engine at takeoff
$2 \cdot 10^{2}$	140	46	Threshold of pain

ultra sound, which is above the range of human hearing. In terms of amplitude, the human hearing covers sound pressures between $10\,\mu\mathrm{Pa}$ (threshold of hearing) and $100\,\mathrm{Pa}$ (threshold of pain) [45].

The static pressure, i.e. the magnitude of the atmospheric air pressure, is not considered part of the sound pressure. Compared to the static pressure, on average at $1.013 \cdot 10^5\,\mathrm{Pa}$, the sound pressure is extremely small.

Sound Pressure Level

Due to the wide dynamic range it is common to express sound pressures as levels. Two different quantities are commonly used as reference quantities p_0 for sound pressures. Either $p_0 = 1\,\mathrm{Pa}$, which is directly the base unit pascal , or $p_0 = 20\,\mu\mathrm{Pa}$. The latter is a conventional reference used in acoustics and was chosen close to the hearing threshold of the human hearing at $1\,\mathrm{kHz}$. This means, a pure sine tone of $1\,\mathrm{kHz}$ with an effective sound pressure of $20\,\mu\mathrm{Pa}$ is just audible to a normal human ear. When this reference quantities is used, the resulting level is canonically referred to as sound pressure level (SPL) and a notation is used, where “SPL” is added as suffix to the dB unit symbol. A sound pressure of $1\,\mathrm{Pa}$ thus results in a level of approximately

$$p = 1\,\mathrm{Pa} \quad \hat{\approx} \quad L_{p/20\,\mu\mathrm{Pa}} = 94\,\mathrm{dB} \quad \hat{=} \quad L_p = 94\,\mathrm{dB\,SPL}.$$

Whereas, if the base unit Pa is used as reference, the resulting levels are

$$p = 1\,\mathrm{Pa} \quad \hat{=} \quad L_{p/\mathrm{Pa}} = 0\,\mathrm{dB} \quad \hat{=} \quad L_p = 0\,\mathrm{dB\,Pa}.$$

Another reference of the SPL to the human hearing lies in the perception of loudness. A change in amplitude of a moderately loud sound is perceived as two times as loud, if the amplitude increase is approximately $10\,\mathrm{dB}$, which corresponds to an increase of power by a factor of 10.

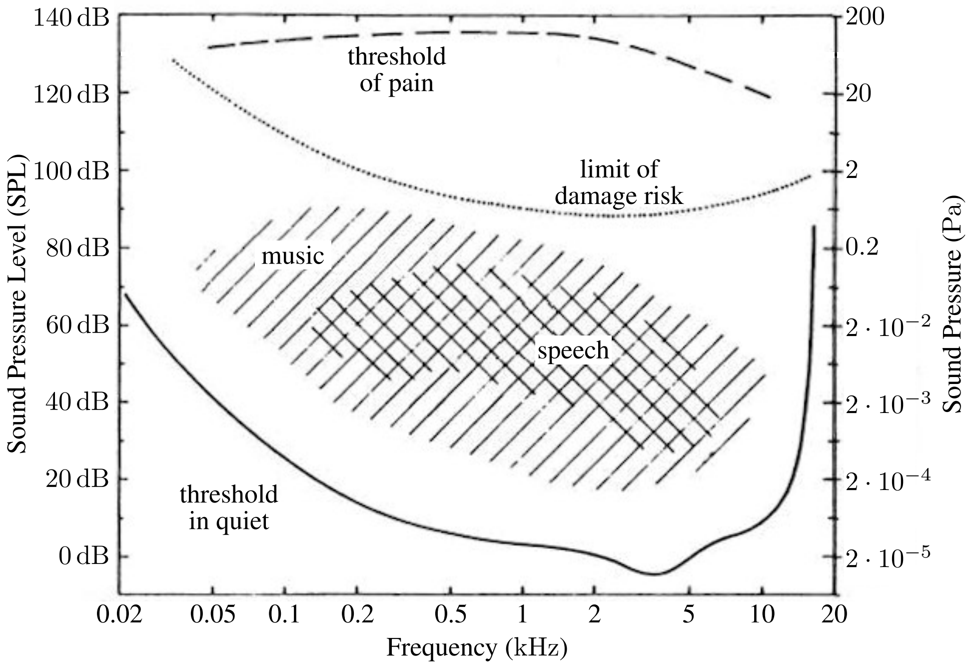


Figure 2.1: Hearing area of the human ear dependent on frequency and sound presssure. Modified from [45].

Table 2.1 lists sound pressures and examples in the range of interest for human hearing. It should be noted, that many other levels and units for sound pressure exist, especially in the context of psychoacoustics and the perceived loudness. Examples are *Sone*, *Phon* and the weighted sound pressure levels, e.g. $\mathrm{dB(A)}$. These also take into account the perceived loudness at different frequencies.

2.2 Hearing

This section gives an overview of the human auditory system and how OAEs are generated. It also highlights which parts are important for OAE detection.

The human auditory system is able to perceive sounds over a wide range of sound pressures and frequencies. Figure 2.1 shows the hearing area of a typical healthy human ear. The area is enclosed by the threshold in quiet (hearing threshold) for low sound pressures and the threshold of pain for high sound pressures. Also visible are typical areas for music and speech. The auditory system can process sound pressures with a dynamic range of $120\,\mathrm{dB}$. At the same time, a change in amplitude of $1\,\mathrm{dB}$ or a change in frequency of $2\,\mathrm{Hz}$ at $1\,\mathrm{kHz}$ can still be discriminated [187]. The human auditory system, especially the neuronal structures which process the incoming nerve signals, is very elaborate. This results in complex behavior, especially when multiple sounds are present, or speech is involved [45].

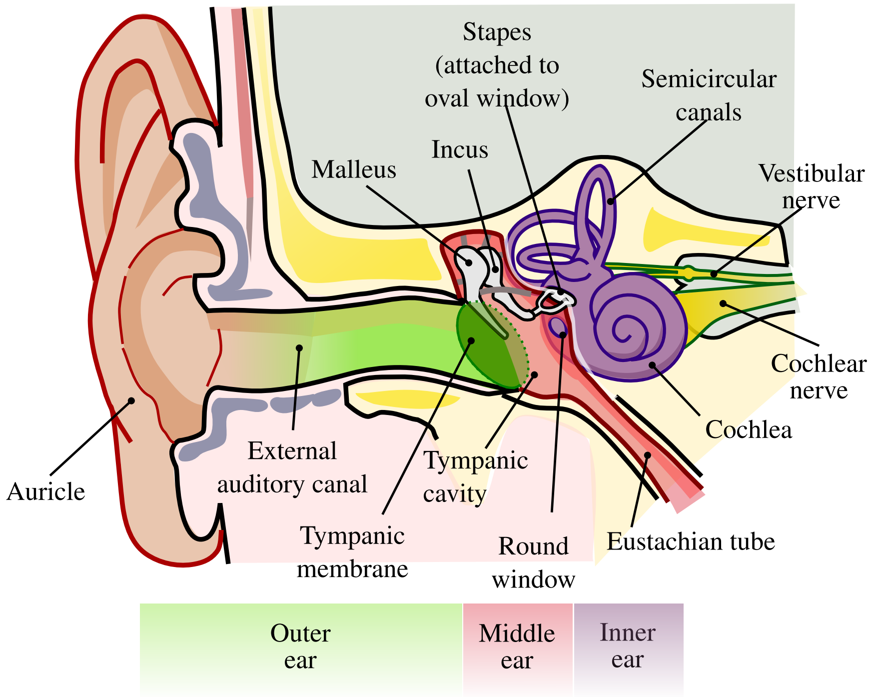


Figure 2.2: Schematic diagram of the anatomy of a human peripheral hearing organ. Modified from [30].

2.2.1 Anatomy and Physiology

The human hearing can anatomically and functionally be grouped into the peripheral auditory system and the neuronal structures [153]. Figure 2.2 gives an schematic overview of the peripheral human auditory system, which can be further divided into outer ear, middle ear and inner ear. The intricately shaped inner ear contains, besides the cochlear, the vestibular system. The vestibular system, consisting of the semicircular canals, is dedicated to the sense of balance, motion and attitude. The main function of the auditory system is the reception, transmission, transduction and processing of acoustic signals towards the perception.

After being transmitted and transduced in the middle ear, the sound pressure received by the outer ear results in the formation of a traveling wave (TW) in the cochlea. This excitation leads to shearing movement of the stereocilia on the hair cells in a frequency specific location on the basilar membrane. The sensory cells excited by this interaction lead to the creation of nerve impulses, i.e. action potentials (APs), which are forwarded into the auditory cortex. Further hearing processing takes places in the associated areas of the cerebral cortex.

In the remainder of this section, a description of each region of the auditory system will be given. A special emphasis is put on the involvement of each part on the generation, measurement and analysis of OAEs.

Table 2.2: Age dependency of ear canal geometry as estimated from acoustic properties by Keefe et al. [78].

Age	Ear canal diameter	Ear canal length	Probe insert length	Residual volume
month	mm	mm	mm	cm^3
1	4.4	14.0	9.0	0.07
3	5.4	16.5	11.5	0.13
6	6.3	17.5	12.5	0.19
12	7.0	20.0	13.0	0.25
24	7.7	21.0	14.0	0.33
Adult	10.4	23.0	11.4	0.48

Outer Ear

Air-based sound enters the hearing system through the outer ear, consisting of the auricle and the ear canal. The outer ear receives the sounds pressure and transmits it to the tympanic membrane, which caps off the ear canal.

The auricle supports the directional hearing, as it modifies incoming sound waves, especially at higher frequencies. This improves the binaural sound processing, particularly with lateral sound sources [12], [114]. The resulting interaural latency, phase and intensity differences are processed already in the brain stem. While the auricle is extremely important for the perception and localization of sounds, it is bypassed in most clinical tests. This is because either headphones are used or because the probe is directly inserted in the ear canal, e.g. when measuring OAEs. However, as auricles are shaped in a wide variety between individuals, they are a limiting influence on the mechanical design of ear probes for acoustic instruments. Ear probes, which need to be inserted into the ear canal, must clear the auricle, which limits the probes maximum allowable size and shape.

The ear canal runs from the auricle to the tympanic membrane and is about $23\,\mathrm{mm}$ long for an adult. Exact length of the ear canal varies between individuals and by exact method of measuring. Ahmad et al. reported an average length of $27.7\,\mathrm{mm}$ with a standard deviation of $4.3\,\mathrm{mm}$ measured with castings of 12 ear canals from 8 adults [4]. Salvinelli et al. reported similar findings with an average $23.5\,\mathrm{mm} \pm 2.5\,\mathrm{mm}$ measured in 140 cadavers resulting in 280 castings [146]. The ear canal is not straight, but has several twists and constrictions. The most pronounced constriction is referred to as the *isthmus*, which is at the transition of the outer cartilaginous part, coming from the auricle, to the inner bony part. The isthmus is located at one third into the ear canal and is about $7\,\mathrm{mm}$ in diameter in human adults [4]. However, the ear canal cross section is rarely found to be circular, but regularly described as oval or pear shaped.

While the ear canal is passive in terms of acoustic behavior, its cavity will assist the hearing perception. An adult ear canal has a resonance peak around $2.6\,\mathrm{kHz}$ [150], if the ear canal is left open. In neonatals, the ear canal is much smaller and as such the resonance peak is close to $6\,\mathrm{kHz}$ and approaches adult values at two to three years of age [90]. However, during the measurement of OAEs, an ear probe will be inserted into the ear canal. This will change the residual ear canal volume and also the acoustic characteristics of the remaining cavity. Further, the acoustic properties will depend on the depth of insertion, as well as the quality of the seal to the environment. Keefe et al. measured wideband impedance and reflection in infants of age 1, 3, 6, 12 and 24, as well as adults with a probe inserted into the ear canal [78]. Using the gained data, length, diameter and enclosed volume were estimated, modeling the shape of the residual ear canal as a tapered cylinder. Table 2.2 shows the results. The residual ear canal volume increases monotonically with age until it reaches approximately $0.5\,\mathrm{cm}^3$ when fully grown. As we will discuss in detail in section 2.4, the residual ear canal volume will have a major impact on the calibration and delivery of stimuli.

The functional state of the outer ear has a significant impact on the sound transmissions to the middle ear. Constrictions of the ear canal, e.g. by cerumen or foreign objects, injuries, inflammatory processes, malformation, as well as pathological changes of the tympanic membrane can lead to conductive hearing loss.

Middle Ear

The function of the middle ear is the transmission and transduction of sound energy from the air at the tympanic membrane to the fluid filled cochlea. The middle ear is located in the tympanic cavity and primarily consists of three ossicles connected in line: *malleus*, *incus* and *stapes*. The malleus is connected to the tympanic membrane. The stapes is attached to the oval window of the cochlea. Both malleus and stapes are connected with the incus and articulate at the joints. This setup acts as a set of levers which implement an impedance converter between the tympanic membrane, with an area of approximately $60\,\mathrm{mm}^2$, and the oval window at the cochlear, which has an area of just $3\,\mathrm{mm}^2$. This corresponds to an area proportion of 1:20. Without this impedance adjustment, most of the sound energy would be reflected at the tympanic membrane. Like the outer ear, the pressure gain in the middle ear is frequency dependent and most pronounced at $1\,\mathrm{kHz}$, with an average gain of $23\,\mathrm{dB}$ [98]. While the middle ear is passive in its normal operation, it has been observed, that the gain is not symmetrical for sounds entering the cochlear and sound leaving the cochlear, i.e. traveling in reverse direction through the middle ear. Dong et al. measured a forward transmission gain of $20\,\mathrm{dB}$ to $25\,\mathrm{dB}$ and a reverse pressure loss of $35\,\mathrm{dB}$ [38]. While this behavior has probably little impact on hearing, it has profound impact on the measurement of OAEs, since the minuscule signals originating in the cochlea are further attenuated in the middle ear. However, even though the middle ear has a very strong frequency dependent behavior, the measured OAE levels in the ear canal remain relatively constant across a wider range of frequencies. This suggests, that the amplitude of OAEs generated in the cochlea is greater at higher frequencies [139].

An increased mass of the oscillating structures in the middle ear due to pathological changes, e.g. an effusion, results in an attenuation of higher frequency components, which leads to a conductive hearing loss at higher frequencies. Changes in friction lead to similar consequences. If the stiffness is changed, e.g. due to otosclerosis where the stapes is fused to the cochlea, low frequency components get attenuated. For normal operation, the middle ear cavity must be filled with air at atmospheric pressure. The eustachian tube, which can open during yawns and swallowing, allows the pressure to equalize. A blockage can lead to pressure differences or a liquid filled middle ear cavity, which results in conductive hearing loss.

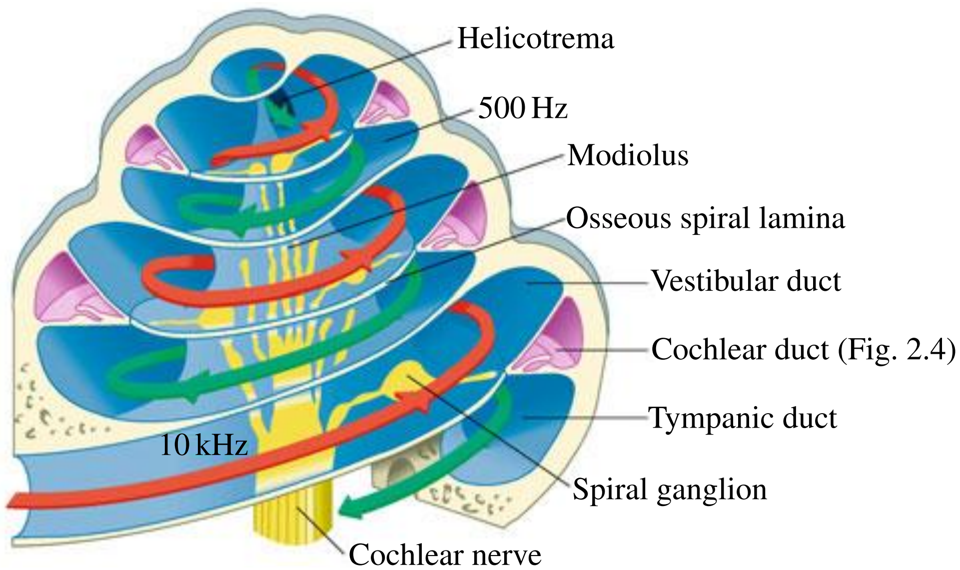


Figure 2.3: Schematic cut through the cochlea along its central axis (modiolus). The three ducts (vestibular duct, cochlear duct and tympanic duct) take approximately 2.5 turns around the modiolus. The vestibular duct and the tympanic duct are connected by the helicotrema at the apex. Modified from [103].

Inner Ear

The final part of the peripheral hearing is the inner ear which consists of a bony labyrinth located in the temporal bone. Besides hearing, the inner ear also contains the vestibular system with the semicircular canals, which serve the sense of balance, motion and attitude, while the hearing sense is served by the cochlea. The cochlea implements the final transduction of the sound pressure in electrical nerve signals, which are carried by the cochlea nerve towards the brain. Sound pressure reaches the cochlea either as the sound pressure in the air, transmitted by the outer ear and middle ear, or to a lesser extend via bone conduction. The cochlea contains the cochlear amplifier, which is responsible for the generation of OAEs.

Figure 2.3 shows the cochlea with its tapered coiled structure and its windings which consist of three fluid filled ducts that spiral around the core (modiolus). The vestibular duct begins at the oval window and the tympanic duct begins at the round window both at the base of the cochlea. The oval and round window (see Figure 2.2) form the junction into the air filled tympanic cavity, with the stapes connected to the oval window.

The vestibular duct and tympanic duct are filled with perilymph and are connected to each other by the helicotrema at the apex of the cochlea. These ducts are separated by a bony shelf, the osseous spiral lamina, which extends about half-way from the modiolus to the outer wall. The second half is occupied by the cochlea duct.

Figure 2.4 shows a closeup diagram of the three sided cochlear duct, which is formed by the vestibular membrane, separating it from the vestibular duct and the basilar membrane, separating it from the tympanic duct. The final side, towards the outer bony shell of the cochlea, is formed by the spiral ligament, where the stria vascularis forms the inner portion. The stria vascularis consists of a delicate network of capillaries and produces the endolymph, which fills the

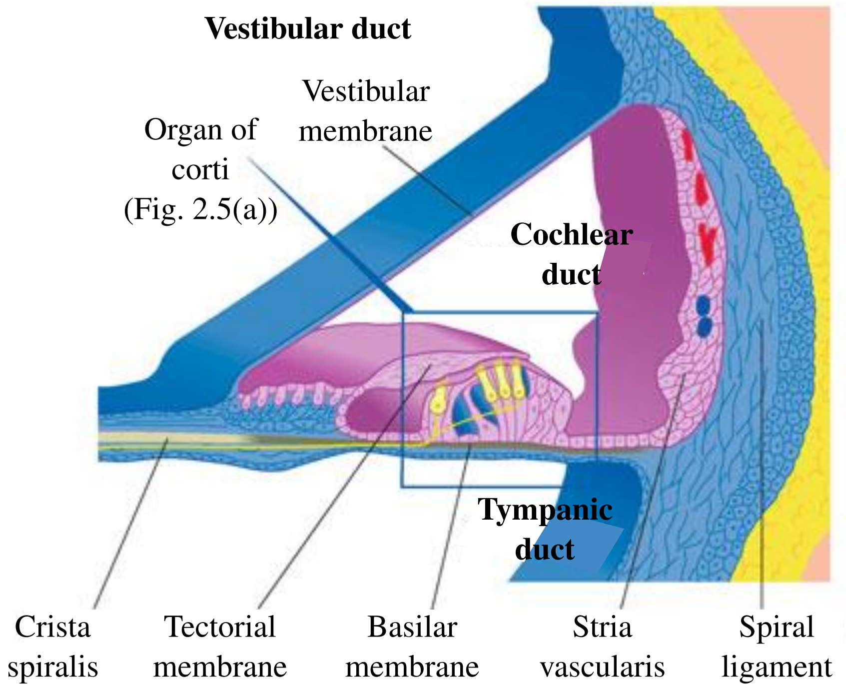


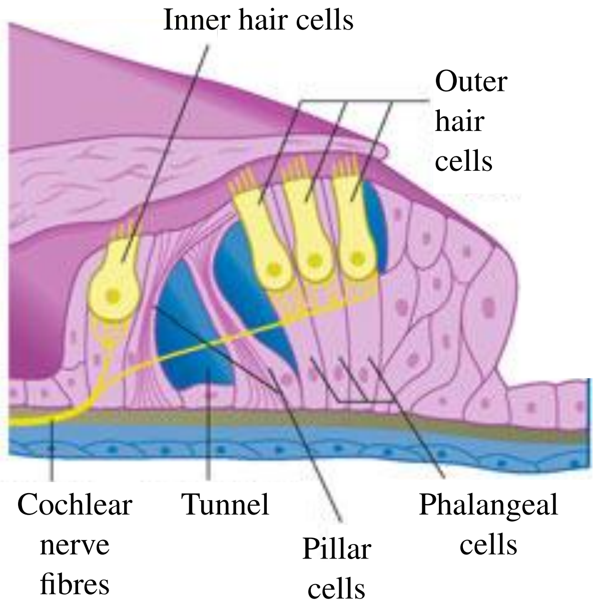
Figure 2.4: Cochlear duct. Modified from [103].

cochlear duct. Due to the cation rich endolymph, a positive electric potential of about $80\,\mathrm{mV}$ to $120\,\mathrm{mV}$ is created, in relation to the perilymph filled vestibular duct and tympanic duct. The vestibular membrane and basilar membrane are tissue membranes and make the cochlear duct elastic, which allows it to move up and down to follow the pressure differences between the two neighboring ducts.

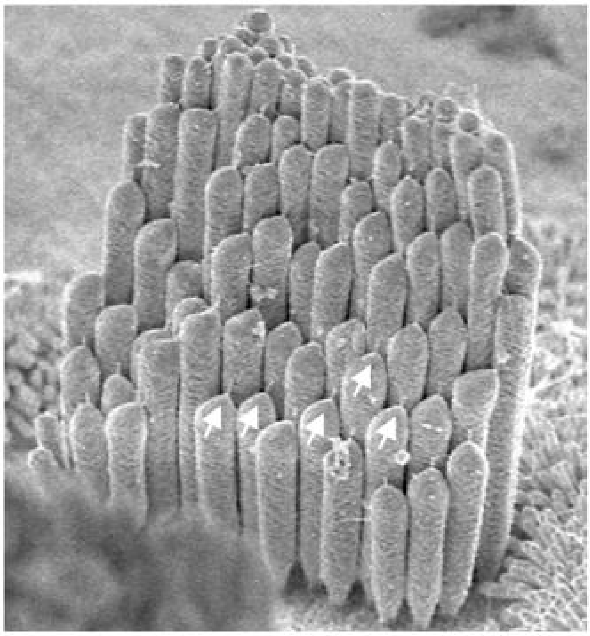
The organ of corti (Figure 2.5(a)) is located on the basilar membrane and contains three rows of outer hair cells (OHCs) and one row of inner hair cells (IHCs). At their tip, the hair cells hold delicate and regularly spaced stereocilia (Figure 2.5(b)) that are connected between each other by tip links and side links [131]. The OHCs and IHCs are embedded into a system of supporting cells. Above the organ of corti lies the tectorial membrane, which covers the organ of corti, starting at the osseous spiral lamina, and contacts the tallest stereocilia of the OHCs, but not those of the IHCs.

The innervation of the organ of corti takes place by efferent (ear to brain) and afferent (brain to ear) nerve fibers of the cochlear nerve, of which the cell bodies form the spiral ganglions. Their axons form the cochlea nerve in the modiolus. As the nerve fibers leave the inner ear, they integrate with the nerves of the vestibular system into the vestibulocochlear nerve.

The basis for the understanding of the mechanical processes in the cochlea is the traveling wave theory established by Georg von Békésy. After the excitation at the oval window at the base of the stapes, a traveling wave is propagating through the cochlea. The basilar membrane, on which the organ of corti is situated, is narrow and stiff at the base of the cochlea, near the oval window. Towards the apex, the basilar membrane gets 10 times wider, 3 times heavier and about 100 times less stiff [14]. During an excitation with an acoustic stimulus, the cochlear



(a) Detailed schematic view of the organ of corti. Modified from [103].



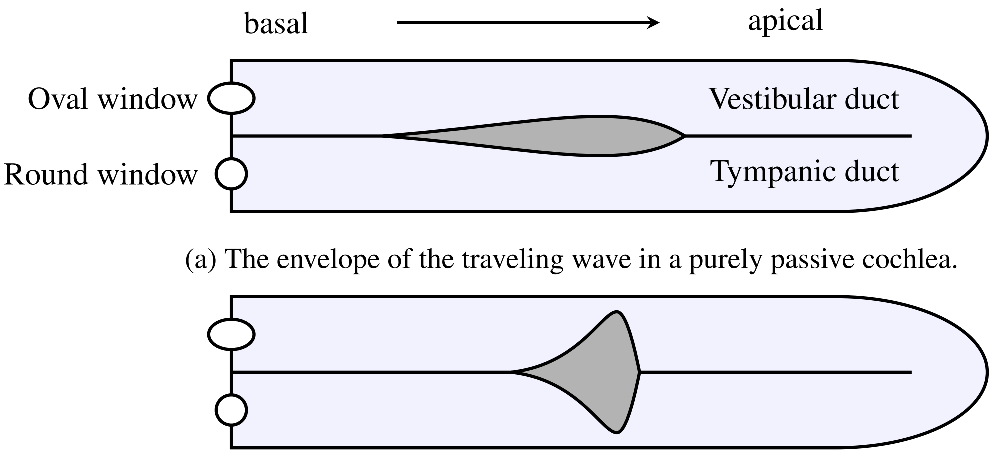
(b) Scanning electron micrograph of the staircase shaped stereocilia of a chicken cochlea. Stereocilia are the mechanosensing protrusions at the end of hair cells. The arrows show the tip links. From [51].

Figure 2.5: Details of the organ of corti.

duct, with all its structures, is moved up and down. Figure 2.6(a) shows the envelope of a pure tone excitation as measured by von Békésy in cadavers.

The location of the maximum on the basilar membrane is dependent on the frequency. The base of the cochlea is more sensitive to high frequency sounds, while the apex of the cochlea is more sensitive to low frequency sounds. Effectively, this leads to a frequency-location translation, also referred to as tonotopic organization. The delay of traveling waves between the highest and lowest frequencies along the approximately $32\,\mathrm{mm}$ long basilar membrane amounts to about $10\,\mathrm{ms}$. The delay of the propagation of the traveling wave, which is utilized in the measurement of transient evoked OAE (TEOAE) (Section 2.3.3), should not be confused with the propagation of sound waves, that only need approximately $20\,\mu\mathrm{s}$ for the same distance in the liquid filled cochlea.

However, these passive mechanical properties cannot be the only reason for the narrow frequency selectivity and wide dynamic range of the human hearing [9], [121]. Active processes in the organ of corti are responsible for the remarkable capabilities of the auditory system. These active mechanical processes are based on the motility of the OHC [23]. Oscillations of the traveling waves are amplified by up to $40\,\mathrm{dB}$. One driver for the motility is the motor protein *prestin*, which can be found in the outer membrane of the OHCs [32]. The OHCs are, additional to this fast motility, also controlled by efferent nerves of the central nervous system.



(a) The envelope of the traveling wave in a purely passive cochlea.

(b) The same stimulus with the active cochlear amplifier.

Figure 2.6: Schematic drawing of an "unrolled" cochlea being stimulated with a single pure tone sine wave.

Both IHC and OHC are embedded into positively charged endolymph of the cochlear duct. Due to the negatively charged hair cell bodies, this leads to a voltage difference referred to as the *cochlear potential*. The up and down movement of the basilar membrane caused by the traveling wave, leads to a relative shift between the organ of corti and the tectorial membrane. The resulting shearing of the stereocilia of the hair cells results in tension on the tip links, which mechanically opens the ion channels near the tips. Cations from the endolymph flow into the cell and depolarize it. In IHCs, this leads to release of neurotransmitters and the generation of nerve impulses (action potential (AP)). In OHCs, the same process triggers the motility, i.e. the change of length, of the cell. The result is a nonlinear amplification of mechanical movements, which is summarized as the *cochlear amplifier*. This amplification improves the sensitivity and terms of amplitude and frequency selectivity. As shown in Figure 2.6(b), when a pure tone stimulus is used in an active cochlea, the amplitude of the traveling wave slowly increases along the basilar membrane, until a maximum is reached, after which the deflection decreases rapidly.

As a side effect, these active processes of the cochlear amplifier result in a mechanical excitation inside the cochlea. This sound energy can then travel backwards through the peripheral hearing system, with all its components working in reverse. The resulting sound pressure signals in the ear canal are referred to as OAEs. This section is intended to give a broad overview of the anatomy and physiology in respect to the generation and measurement of OAEs. The excitation and measurement of OAEs for clinical purposes and their generation in cochlea is discussed in the next section.

Further details of the inner workings of the auditory system are well beyond the scope of this work. Additionally, the exact understanding of the active processes surrounding the cochlear amplifier and their link to the generation of OAEs are still up for debate. Recent reviews of this discussion are available by Ashmore et al. [9], Bowling et al. [19] or Avan et al. [10].

2.3 Otoacoustic Emissions

This section introduces the classification of otoacoustic emissions (OAEs) and presents the relevant measurement protocols used in hearing screening applications. As discussed in Section 2.2, OAEs are produced by the cochlear amplifier in the inner ear. When an OAE is detected in the outer ear, conclusions can be made on the condition of the auditory system.

All OAE measurements have in common, that they are measured using an ear probe of which the tip is inserted into the ear canal. The ear probe consists of several transducers, i.e. one or more speakers and at least one microphone. Often, the transducers are integrated into the ear probe body, but the transducers can also acoustically be connected via a tube. An important factor for the success of the measurement is the probe fit in the ear canal. It must seal the ear canal to the environment, but also allow an unobstructed acoustical connection to the tympanic membrane for the transducers. Since the sound pressure of the OAE itself is minuscule, it can easily be drowned in noise. Noise originates from ambient or physiological (breathing, swallowing, etc.) sources. The instrumentation and how it can support managing stimuli delivery, probe fit and noise, are discussed in Section 2.4.

While OAEs can occur spontaneously, they are usually evoked by an external acoustic stimulus, in which case they are referred to as evoked OAE (EOAE). Stimulation can be performed with a wide variety of stimuli. However, only a narrow set is used in research, diagnostics and hearing screening. OAEs are usually classified by their stimulus type. Common are spontaneous OAE (SOAE), stimulus frequency OAE (SFOAE), distortion product OAE (DPOAE) and transient evoked OAE (TEOAE), where the latter two are the most relevant in hearing screening. However, the first two can be used to highlight the motivation for the usage and prevalence of TEOAE and DPOAE in diagnostics and hearing screening.

While both SOAE and SFOAE are suitable to detect hearing loss, and are regularly used for clinical research, these measurement protocols are not very common in hearing screening. For SOAE, this can be mostly attributed to the lack of specificity and the susceptibility to environmental noise. More importantly, both protocols require a longer measurement time for a conclusive hearing screening result. Especially in hearing screening of neonates and small children, the measurement time must be as short as possible. Both, TEOAEs and DPOAEs, can be measured faster and more reliably within their individual limitations.

2.3.1 Spontaneous OAE

Spontaneous OAEs (SOAEs) can be recorded in the outer ear canal, without any active stimulus of the cochlea. The measured OAEs are usually detectable as one or more narrow peaks below $6\,\mathrm{kHz}$. While earlier studies estimated a prevalence in human ears of less than $40\,\%$, more recent results show a prevalence of up to $80\,\%$ [97]. However, the increase is attributed to improved instrumentation over the years, as the reported SOAE levels are usually well below $0\,\mathrm{dB\,SPL}$, depending on the measurement method. Additional to the truly spontaneous recordings, another method is to precede the recording with a transient click stimulus. Recordings are then taken in the window of $20\,\mathrm{ms}$ to $80\,\mathrm{ms}$ after the click. This allows the measurement to be quickly repeated, thus lowering the noise floor, and is referred to as synchronized spontaneous OAE (SSOAE). SOAEs and SSOAEs show approximately similar behavior [170].

2.3.2 Stimulus Frequency OAE

SFOAEs are recorded with a single pure sine tone as stimulus. Depending on the applied sound pressure, the cochlear amplifier will amplify or attenuate in a non-linear manner, which, by itself, generates OAEs. However, due to the generated OAEs being at the exact same frequency as the stimulus, the OAEs and the stimulus sound pressure in the ear canal can not directly be separated. The strategies to extract the SFOAE signal, usually involve sequentially applying different stimuli conditions. Either the stimulus is applied at two different levels (compression method), to which the cochlear amplifier will react differently, or a suppressor tone close to stimulus frequency is added (suppression method). In both cases, the generated SFOAEs will be at different levels, while the stimulus either did not change at all or changed in a linear and predictable manner. Comparing both recordings by subtracting amplitude and phase at the stimulus frequency yields the SFOAE signal. Experimental results show, that both methods perform approximately identical [75]. For a meaningful hearing screening result, multiple frequencies need to be probed sequentially.

2.3.3 Transient Evoked OAE

The stimulation of TEOAEs, sometimes also referred to as click evoked OAEs (CEOAEs), is based on a short duration click impulse. As this impulse propagates onto the basilar membrane, it results in an excitation of almost the entire cochlea, due to its broadband nature. This sudden excitation allows the measurement of OAE responses in a single measurement over all frequencies relevant for hearing screening [82]. As the click enters the cochlea at the oval window, it starts to excite the basilar membrane. Since the basilar membrane is sensitive to high frequency excitation at the base of the cochlea, the high frequency components of the stimulus click will lead to a maximum of excitation at this location. As the click stimulus propagates further into the cochlea, lower frequency components start to interact more intensely with the basilar membrane, until the apex is reached. The result is, that the individual frequency component of the short duration wide-band click are mapped to locations on the basilar membrane (tonotopy). The cochlear amplifier amplifies or attenuates the sound at each location in a non-linear manner. The resulting movement of the tectorial membrane stimulates the IHCs, but also releases some sound energy, which then travels backwards through the cochlea. The high frequency response arrives almost immediately at the oval window, since it is processed at the base. Lower frequency components, which are processed closer to the apex, take several milliseconds to propagate back to the oval window. This results in a mapping of frequency to time.

If the resulting response in the ear canal is captured as a time domain signal, it approximately contains the high frequency components first and the low frequency components last [112], [136]. Additionally, an echo response of the stimulus is contained in the signal. Due to the delayed nature of the OAE response, this stimulus artifact appears only at the very beginning of the response. However, reverberation of the click stimulus overlaps with the highest frequency

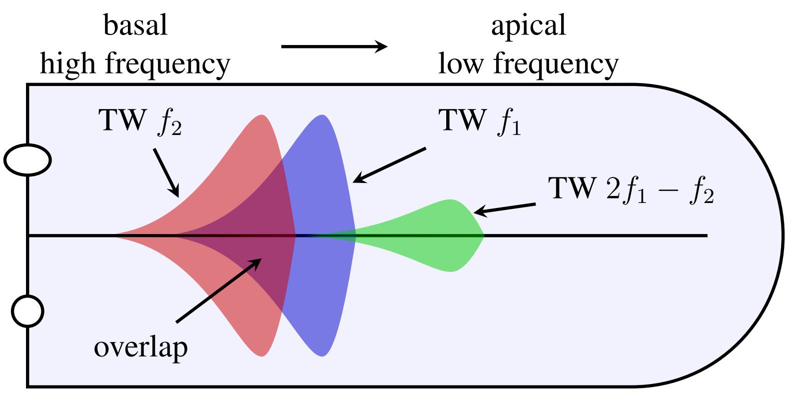


Figure 2.7: Schematic representation of the excitation envelopes of the traveling wave (TW) on the basilar membrane during a DPOAE measurement.

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components, which appear first in the response. This overlap is the primary upper frequency limitation when measuring TEOAEs, at about $4\,\mathrm{kHz}$. Due to the broadband character of the measurement, it is very sensitive to environmental noise. Ambient noises coming from e.g. air conditioners, conversations or traffic can quickly raise the noise floor. In noisier conditions, narrow band measurement protocols, i.e. SFOAE and DPOAE, have an advantage. However, under normal conditions, the exclusive measurement duration (i.e. not including preparation and probe placement) can be approximately $15\,\mathrm{s}$, and can be as low as $2\,\mathrm{s}$, if strong OAEs are present [125].

Moreover, the measurement of TEOAEs usually includes specific pulse sequences to extract the non-linear components. Details on the measurement and the used procedures in this work will be presented in Section 2.4.7.

2.3.4 Distortion Product OAE

The main drawback of measuring SFOAEs is that the cochlear response is at the exact same frequency as the stimulus. Thus, separating stimulus artifact from actual response is a central problem. When measuring TEOAEs, the problem of distinguishing stimulus from response is solved by separating both in time domain. For the measurement of DPOAEs, the cochlear amplifier is stimulated with two sine wave tones, such that an intermodulation distortion (IMD) occurs. This results in signal components occurring at frequencies, which are not at the stimulus frequencies or its harmonics. The two DPOAE stimulus (or primary) tones are referred to f_1 and f_2 with $f_1 < f_2$. Any signal component occurring at frequencies that are not part of the stimulus, must have another active source in an otherwise linear and time-invariant (LTI) system. The IMD occur if both stimuli tones are so close to each other in frequency, that the envelopes of the respective traveling waves on the basilar membrane are overlapping, see Figure 2.7. The resulting non-linear intermodulation at the overlap is a purely mechanical process on the basilar membrane. The OAEs generated in the overlap area are the primary source of the resulting OAE signal in the ear canal. The frequencies of the resulting DPOAEs are in an arithmetic relationship to the frequencies of the stimulus tones, with $f_{DP} = f_1 + N(f_2 - f_1)$ where N is

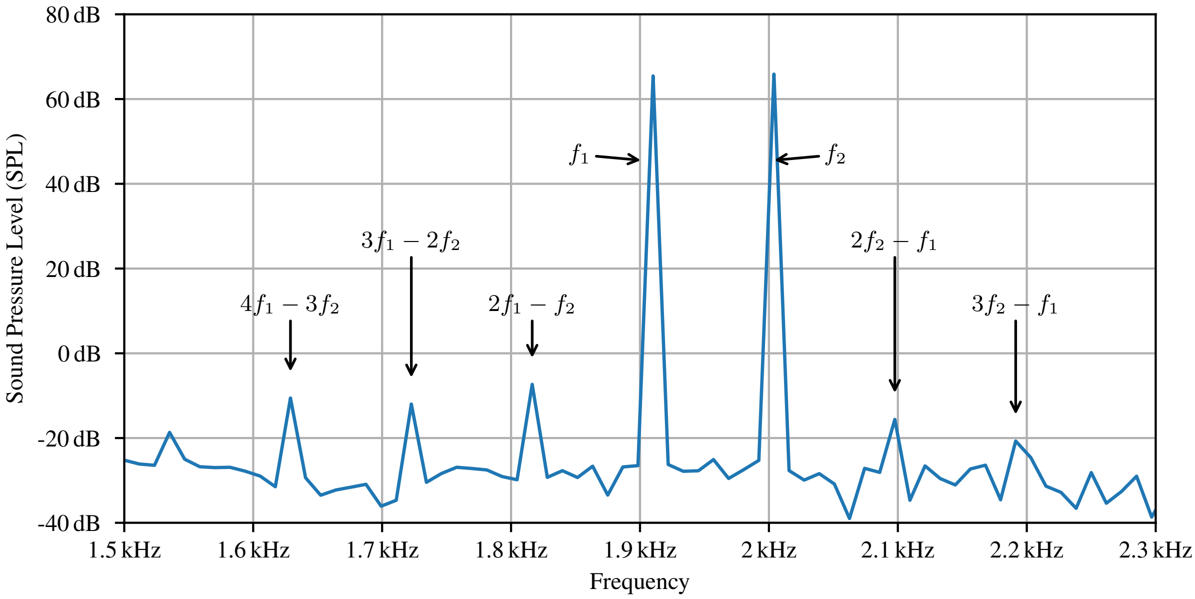


Figure 2.8: DPOAE recording in a healthy human ear. Multiple DPOAEs are visible in a fixed arithmetic relationship, based on the distance of the two stimulus tones f_1 and f_2.

an integer [86]. Figure 2.8 shows an example recording in a healthy human ear, were multiple DPOAEs are generated, such as $3f_1 - f_2$, $2f_1 - f_2$, $2f_2 - f_1$ or $3f_2 - f_1$. However, usually $f_{DP} = 2f_1 - f_2$ is the strongest in human cochleas and is the most commonly observed one in hearing diagnostics and screening.

The primary source of the DPOAE signal is the overlap region, close to the characteristic region of f_2 [94]. However, the generated DPOAE frequency components will also interact with their own characteristic regions on the cochlea. At this place, the cochlear amplifier will also interact with the TW and emit a DPOAE of the same frequency. The OAEs of these two sources will interact with each other, leading to constructive and destructive interference [60]. Small changes in phase or frequency of the stimuli signals can lead to a significant change in amplitude of the DPOAE signal in the ear canal and is referred to as the *fine structure*. Two common strategies to mitigate this effect are a suppressor tone close to the measured DPOAE frequency or frequency modulation (FM) of the primary tones [110]. It should be noted however, that the exact mechanism of how the energy at each place is released or dissipated is still up for discussion [19].

2.4 Measuring Otoacoustic Emissions

In the preceding sections, the physiological background of OAEs and OAEs themselves have been discussed. This section introduces the technical and instrumentation aspect of using OAEs for hearing screening. Since OAE-based hearing screening has been widely adopted, many scientific and commercial devices are available today. Figure 2.9 shows a generic high-level overview of such a device. The OAE screening device, which is often handheld and battery

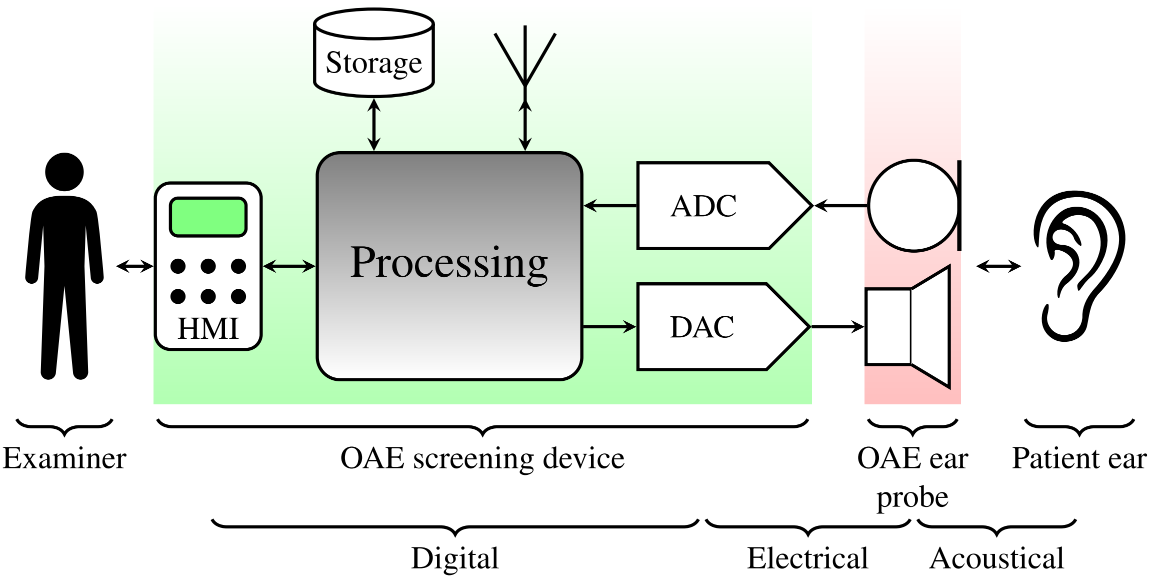


Figure 2.9: Schematic overview of an OAE hearing screening device. Most functionality is provided by the central "processing" system in digital domain. The main exception are the input and output paths to interface the system with the ear of the patient via an OAE ear probe.

powered, is usually connected to the OAE ear probe via a cable. The probe itself is inserted into the ear canal of the patient. The device is controlled by an examiner, who will prepare the measurement (i.e. perform an otoscopy, insert the probe into the ear, etc.), and subsequently start and monitor the measurement. On basic screening devices, the result will be shown as a summary or simply as "pass"/"refer". Additional information is usually given in the form of stability and noise levels during the measurement.

The remainder of this section introduces the relevant concepts of OAE hearing screening devices and highlights the algorithms used in the following chapters.

2.4.1 Measurement System

As shown in Figure 2.9, an OAE screening device is usually built around a central processing block, which performs all controlling, digital signal processing (DSP) and interfacing tasks with the various other components. With this topology, all processing functionality can be implemented in a single DSP or microcontroller integrated circuit (IC), thus lowering cost and complexity. Only moderate performance requirements, in terms of processor speed and random access memory (RAM) are necessary for simple OAE screening algorithms. However, significantly more performance might be needed for elaborate human machine interfaces (HMIs) or other peripheral tasks, e.g. connectivity. Requirements of the processing system will be discussed in Section 3.3.

The measurement system needs to interface acoustically with the ear of a patient. The signal paths, coming from the microphone and going out to the speakers, form another essential component. The transducers in this chain allow the digital processing system to acoustically interface the patients ear canal, generate the stimuli and record the OAE responses as discussed in Section 2.3. The OAE ear probe implements the immediate transduction of the incoming and outgoing signals. The built-in speaker will convert the electrical signals into acoustic signals, which form the stimulus for the OAE recording protocols. The speaker is connected to an digital-to-analog converter (DAC), usually with an appropriate amplifier in between, to reach the required acoustical output power. The reverse direction is implemented by a microphone, which converts the acoustical sound energy in the ear canal into an electrical signal. After some pre amplification, the signal is converted to digital domain with an analog-to-digital converter (ADC). The signal transduction from digital to electrical domain including the amplification can be implemented with individual components. However, due to continuing trends in smartphones and other multimedia devices, all functionality of this path can be represented by a single audio codec IC. These ICs contain a digital interface, usually multiple DACs and ADCs, as well as appropriate amplifiers, which can also be digitally controlled.

The human machine interface (HMI) must offer the connection between the measurement system and the examiner. As can be seen in Table 2.4 the minimum requirements for the HMI of a hearing screening device are very basic. Only very few input signals are needed, e.g. a trigger to start the measurement. Configuration of the measurement is stored in the system and all measurement steps are automatically performed by the device. On the return path, from the system to the examiner, the result can be displayed as a simple “pass” or “refer”. However, since the OAE screening measurement can fail, and result in a “refer”, even though the measured ear is healthy, additional information is usually given, even by screening devices. Displaying a measure of noise levels during the measurement and a measure of the stability of the measurement can help to rule out certain problems with the measurement before referring the patient to a full diagnostic test. Further, the measurement system can detect certain faults by itself (e.g. a blocked microphone, leaky probe fit, etc.) by inspecting the recorded response or with a dedicated in-ear calibration (IEC) procedure. The results and, if possible, also instructions to the examiner on how to solve the issue can also be communicated through the HMI. Since the success of the measurement is dependent on the environmental conditions and the careful conduction by the examiner, a well designed HMI can improve the pass-rate of a device by guiding the examiner through the steps and giving appropriate feedback. Actual components of the HMI on screening devices are usually liquid crystal display (LCD) or light emitting diode (LED) screens in conjunction with buttons or touch inputs.

Feature rich screening devices also include a storage, which is mostly used to store patient data and measurement results. However, this functionality usually also requires a more substantial HMI to be able to enter and modify patient data as well as display the results. In more interconnected environments, like clinics, a (wireless) communication interface can be used to digitally manage patient records by connecting the device to a network directly or via a gateway, e.g. a smartphone. Used technologies include universal serial bus (USB), near field communication (NFC), Bluetooth, Bluetooth low energy (BLE) and Wi-Fi.

The introduced components of an OAE measurement system so far only include those related to signals and information. Not shown in the overview diagram is the power supply, which in screening devices is often implemented by a battery. When the battery is rechargeable, charging, battery management and power management systems are additionally present.

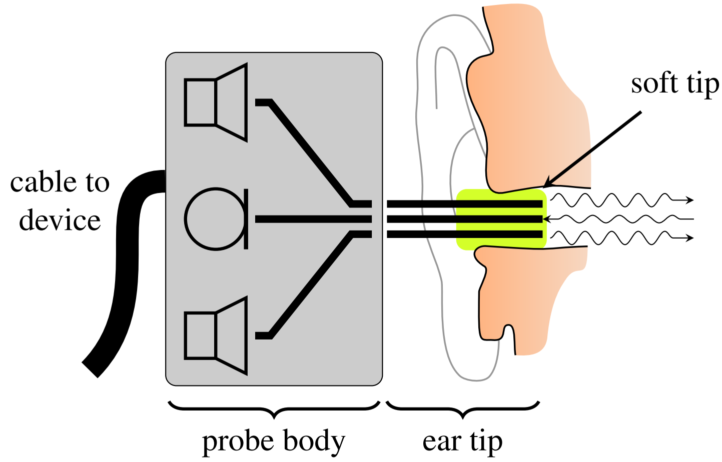


Figure 2.10: Components of a DPOAEs ear probe with two stimuli speakers and a recording microphone. The ear probe is connected to the measurement device with a cable. The ear tip, which connects the probe body with its transducers to the ear, is usually detachable and replaced between each patient. To achieve an airtight connection to the ear canal, the tip is fitted with a soft material, e.g. foam.

OAE Ear Probes

A key component in every OAE measurement system, be it for diagnostic or screening applications, is the OAE ear probe. As already introduced, it establishes the connection of the measurement system to the patients ear and houses the transducers, to convert the electrical signals into acoustical signals and vice versa. OAE ear probe designs have to be optimized for several goals, which are discussed next.

Since the probe needs to deliver stimulus to the ear drum and record the OAE response, the probe's transducers must exhibit a useful frequency response, which should ideally be flat in the relevant frequency range (up to $8\,\mathrm{kHz}$). Additionally, the microphone needs to be sensitive enough, so that it is capable of detecting the minuscule OAE responses, while maintaining an appropriate signal to noise ratio (SNR). The requirements for the speakers are less strict, since their frequency response can be compensated by the measurement system in most cases. Sound pressure output levels can be adjusted by changing amplifier settings or numeric amplitudes in the DSP. However, care must be taken, that the stimulus does not contain distortions, which could be detected as OAE. For that reason, a DPOAE ear probe must contain two speakers, one for each primary tone, as shown in Figure 2.10. If both primary tones were played from the same speaker, it would generate IMDs, which were not easily distinguishable from a DPOAE response. Generally, all transducers of the probe should behave in an LTI manner, which simplifies the algorithms and makes the signal analysis more reliable and predictable.

Since the OAE ear probe is in contact with the ear canal, several additional aspects need to be considered. As discussed in Section 2.2.1, the outer ear is not at all uniform across the population. For example, just the ear canal diameters varies from $4.4\,\mathrm{mm}$ to $10.4\,\mathrm{mm}$, depending on age. However, the probe must be fitted into the ear canal, such that an airtight seal to the environment is created. This is necessary to keep the weak sound energy of the

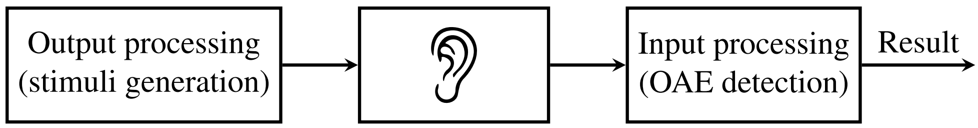


Figure 2.11: High-level signal processing components of an OAE measurement, during which stimuli generation is mostly independent of the input processing.

OAE contained, but also to attenuate the environmental noise reaching the probe microphone. The solution chosen by most manufactures is to have a detachable probe tip. These probe tips are manufactured from various soft materials (e.g. rubber, silicone, foam, etc.) and come in different sizes to fit neonates and adults alike. At the same time, this replaceable tip facilitates hygiene, since it can be discarded after every patient. Probe fitting, including tip selection, is one of the difficulties when measuring OAEs. An experienced examiner can conduct measurements quicker and with a lower refer rate, due to better tip selection and probe fitting. Finally, since the probe has small channels that conduct the sound pressure from the transducers into the ear canal, they can get blocked, either by facing against the ear canal wall or by materials such as cerumen and other debris. This can result in a permanent blockage of a transducer channel, meaning it must be possible to clean the channels. Which is, depending on the design, either possible by disassembling the probe or simply by taking of the ear tip.

Since ear probes need to fit into the ear canal, they must also clear the auricle while inserted. This means that smaller probe bodies are preferable or at least that it should taper towards the ear canal. A lightweight probe, with a center of mass close to the ear canal, will also help the probe to remain fixed, even with forces from gravity or the probe cable acting on the probe body.

It should be noted that it is feasible to measure OAEs with an unsealed ear canal [17], [177]. However, sealed measurements usually yield conclusive results faster and more reliable compared to unsealed systems. However, the ambient noise can, be it a sealed or unsealed measurement, be reduced by using circumaural hearing protection, i.e. over-ear earmuffs.

2.4.2 Input and Output Processing

Figure 2.11 shows a high-level overview of the signal processing blocks involved in an OAE measurement. As discussed in Section 2.3, the stimulus signals do usually not change during the actual OAE measurement. For the most part, the stimulus signal can be computed before the actual measurement starts, e.g. the sine waves for stimulating DPOAEs. Even the output levels of the stimulus could be computed beforehand, as discussed in Section 2.4.4.

The majority of signal processing is dedicated to analyze the recorded input signal of the microphone. The overall goal is to identify, whether an OAE is present in this input signal. Since the signal of interest is usually well below the noise floor, several steps for noise reduction need to be performed as well. Figure 2.12 shows the necessary steps, starting from capturing samples from the ADC. Details on the individual processing steps are discussed in the following sections. It should be noted, that the details of each step are not only implementation dependent, but also application specific. For example, the input processing chain for TEOAEs does not

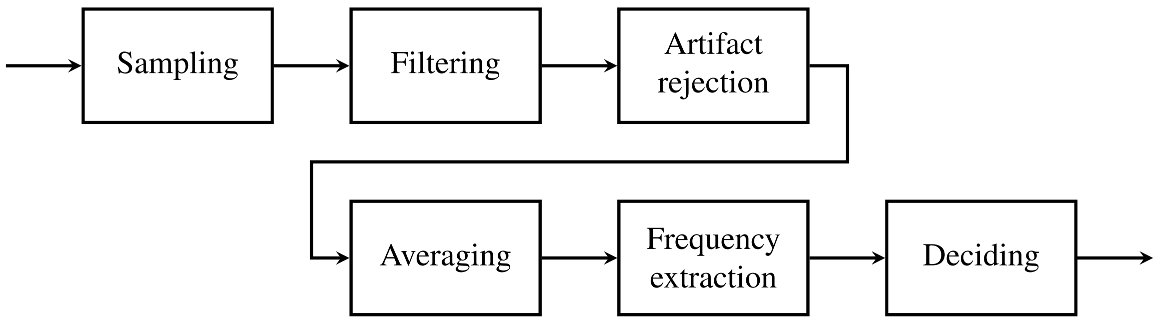


Figure 2.12: Generic input processing chain used in OAE screening devices.

necessarily need a frequency extraction step, since all steps could also be accomplished in time domain. Further, a strict one-way flow is also not mandatory, since feedback loops may be used, e.g. for adaptive filtering.

In this work, processing is always considered in terms of buffers, with a fixed number of samples N each. Samples arrive as buffers $x_m(n)$, where n ($0 < n \leq N$) denotes the sample position in the buffer and m ($0 < m \leq M$) is the sequence number of the buffer where M is the total number of buffers recorded. The buffer size N can be different for each processing step. For example, if the filtering step implements down sampling by a factor of two, the buffer length at the output will be $N_{filter,out} = N_{filter,in}/2$.

Sampling The sampling block does not involve any signal processing by itself. This step moves the data from the digital interface of the ADC into RAM and as such will mostly contain memory access operations. For each input buffer recorded from the ADC, an output buffer of constant content and equal length is played by the DAC in a synchronous fashion. This synchronous input/output sampling is the basis for the following analysis.

Filtering The incoming signal is band-pass filtered, to remove frequency components that are outside the area of interest. This is especially necessary, if the signal is not analyzed in frequency domain later, e.g. when measuring TEOAEs. To reduce system load, this step could also contain down sampling.

Artifact rejection Noise does not only occur as continuous uncorrelated noise, but also as short duration disturbances (e.g. swallowing, door closing, etc.). Signal buffers with such disturbances must be handled appropriately before averaging, otherwise the noise floor increases dramatically by including these signal components. The affected buffers are either discarded, or get a weight assigned, which will be applied during the following averaging steps.

Averaging The signal of interest is usually not detectable outright in the raw signal, because it is below the noise floor. If all measurement parameters are within their normal limits, the noise components are mostly mean-free, random and uncorrelated. As a result, averaging multiple buffers will lower the variance of the signal. The recorded input signal will also contain the stimulus. However, if sampling of output and input are synchronous, it will have not further influence on the averaging step.

Frequency extraction This step is the extraction of frequency components. For example, when measuring DPOAEs, this step is needed to extract the $2f_1 - f_2$ and possibly neighboring frequencies, which are used in the next step to calculate a SNR. This step could be implemented with a discrete Fourier transform (DFT) if the full spectrum is needed or using the Goertzel algorithm [127] for individual components. As a result, this step can be used to greatly reduce the buffer length N by discarding the signal components that are not relevant for the following steps. Finally, the frequency extraction step can be reordered, depending on the specific implementation and application. Barring only numerical errors, time domain and frequency domain averaging are equivalent. Thus, early frequency extraction offers potentials for lowering processing load and memory requirements.

Deciding This final step is used to decide, whether the OAE signal is present and in general on the state of the ongoing measurement. This includes noise levels, stability, elapsed time, SNR of the OAE and eventually the “pass”/“refer” result. Results of this block are used to control the measurement at runtime: If the SNR of the OAE exceeds a threshold, the measurement can be stopped and a “pass” issued. If a time limit is exceeded, a “refer” will be issued. If noise or stability criteria threshold are exceeded, the measurement might be aborted.

The data rate between two components is generally reduced further along the processing chain. Looking at the beginning and the end of the input processing chain, samples might be read from the ADC with a sample rate of $f_s = 48.000\,\mathrm{Samples/s}$. However the final output will output only a few $\mathrm{bits/s}$, containing the state of the measurement and overall result (i.e. “pass”/“refer”).

The data rate is lowered not only by the processing occurring in the steps themselves (e.g. down sampling, frequency extraction). In addition to the changing buffers size, the individual steps can also have differing update rates. Building on the last example, if samples are read from the the ADC interface at a buffer size of $N_{in} = 1024$, the resulting buffer update rate is $f_{b,in} = f_s/N_{in} \approx 47\,\mathrm{Hz}$. However, there is little benefit to execute the deciding step at this same rate, since a delay of $1\,\mathrm{s}$ might not be noticeable by the patient or the examiner. As a result, executing frequency extraction and deciding at a lower update rate, will decrease the processing load. This lower buffer rate at the tail of the input processing chain would also be “free”, since the averaging step already accumulates the incoming data. Just the analysis of the averaged data is delayed/less frequent. Section 3.3 discusses the implications of these decisions in the system design of a low-cost hearing screening device.

In an actual screening usage, the processing occurs in real-time. The decisions might be constrained by limited computing resources like RAM or central processing unit (CPU) time, especially in low-cost applications. However, in other applications it can be useful to interrupt the input processing chain and extract the data. This can either be done for computational offloading or for offline analysis of the data. In the latter case, it is desirable to extract the data after the sampling step. The processing chain can then be executed multiple times on the same data, for example to test and improve the used algorithms and parameters. This offline approach is followed in Chapter 4.

The discussed input processing chain might be used, with some alteration, to measure either DPOAEs or TEOAEs. However, even though there is usually less emphasis necessary on noise reduction, a similar input/output processing chain can also be used for the calibration and more specifically, the in-ear calibration, which both will be discussed next.

2.4.3 Calibration

All sound pressures in an OAE screening device are represented by numerical values during the digital signal processing. As discussed later, the actual physical quantities are often not required, since only ratios of values are needed, e.g. when considering the SNR of an OAE measurement. However, to properly evoke the OAEs, the tympanic membrane needs to be excited with the appropriate sound pressure levels. Meaning, at least during stimulus generation, a proper relationship of numerical values to sound pressure needs to be established. The goal of the calibration is identifying the transfer function of the involved components, such that for a given digital signal value a corresponding sound pressure can be found and vice versa. For the input path, this includes the ear probe microphone and the ADC. Naturally, each of the components has its own transfer function, which also translates from one physical quantity to another, i.e. the microphone transfer function H_{Mic} translates from sound pressure to voltage, the ADC transfer function H_{ADC} from voltage to dimensionless numerical values. This results in the input transfer H_{in} function of

$$H_{in} = H_{ADC} \cdot H_{Mic}.$$

The transfer function of the ADC, which also includes the preamplifier, is ideally a constant amplification across all relevant frequencies and can reasonably well be attained from the involved components specifications, or simply be measured. Microphones, however, have a much higher variance between parts. Further, due to the integration of the microphone into the ear probe body, the frequency response is altered. Finally, the microphone might be subject to drift, e.g. over time or by temperature. These factors necessitate a calibration of each OAE ear probe microphone.

Calibration data can be obtained with free-field measurements and a reference microphone. However, OAE ear probes can be calibrated most conveniently in a small cavity, which is similar in dimension to an ear canal. A direct approach is inserting the probe into a sound level calibrator, which is a fixed frequency and fixed sound pressure sound source. These devices usually generate a sound pressure of $94\,\mathrm{dB\,SPL}$ (i.e. $1\,\mathrm{Pa}$) at $1\,\mathrm{kHz}$. Obviously, this only yields the sensitivity of the OAE ear probe microphone at this one fixed frequency. However, measurement at much higher frequencies would not yield usable results, due to standing waves between the probe and the calibration sound source causing interference.

A possible procedure for the full frequency range calibration was described by Siegel [152], as well as Rasetshwane and Neely [141]. In this procedure, a syringe with an internal diameter of $8\,\mathrm{mm}$ is used as a small artificial cavity, similar in size to that of a human ear canal. A speaker is inserted in the first opening. A small tube microphone is radially inserted close to the second opening. A reference microphone with a known frequency response, e.g. a sound level meter (SLM), is inserted into the second opening. In this configuration a broadband signal, e.g.

a linear chirp, is generated with the speaker in the first opening. At the same time, the reference microphone response U_{ref} and tube microphone response $U_{tube,ref}$ are recorded. This yields the transfer function

$$H_{ref/tube,ref} = \frac{U_{ref}}{U_{tube,ref}}. \tag{2.4}$$

The reference microphone is removed and replaced with the OAE ear probe under test. Generating the same broadband signal on the speaker again yields the OAE probe microphone response U_{probe} and a second tube microphone response $U_{tube,OAE}$, as well as their transfer function

$$H_{OAE/tube,OAE} = \frac{U_{probe}}{U_{tube,probe}}. \tag{2.5}$$

This allows to obtain the transfer function of the OAE probe microphone relative to the reference microphone

$$H_{probe/ref} = \frac{H_{probe/tube,probe}}{H_{ref/tube,ref}} = \frac{U_{probe}}{U_{tube,probe}} \cdot \frac{U_{tube,ref}}{U_{ref}}. \tag{2.6}$$

Since the frequency sensitivity of the reference microphone S_{ref} is known, the frequency response or sensitivity of the OAE probe microphone S_{probe} can now be obtained by

$$S_{probe} = H_{probe/ref} \cdot S_{ref}. \tag{2.7}$$

This procedure is used for the calibration of probes in Chapter 5.

Since ear canal volume and impedance vary between each ear probe insertion, a general valid relationship between digital output level and sound pressure output level can not be given. This problem is further confounded by standing waves in the ear canal, which lead to differing sound pressures at the OAE ear probe microphone and the tympanic membrane. The problem of generating a defined sound pressure at the tympanic membrane in an acoustically unknown environment (the patients ear canal) is discussed in the next section.

2.4.4 In-ear Calibration

For reliable detection of OAEs, the stimulus sound pressure at the tympanic membrane must be set within a certain margin of error. This process is referred to as in-ear calibration (IEC). As discussed in Section 2.2.1, the outer ear canal serves as the acoustical interface between the environment and the auditory system. However, the ear canal is not formed uniformly and its length, size and shape vary between individuals. By inserting the OAE ear probe into the ear canal during the measurement, a small cavity between the ear probe and the tympanic membrane is formed. This remaining cavity is referred to as residual ear canal volume. As already discussed, the advantages of this setup are lower ambient noise at the probe microphone and better containment of the OAE signal energy. However, due to the geometry of the residual ear canal volume standing waves become a problem.

Ear Canal Standing Waves

Standing waves in the ear canal leads to interference during OAE measurement. The sound pressure waves generated by the ear probe speaker (incident waves) are only partially transduced by the tympanic membrane. The remaining sound pressure is reflected and travels backwards in the direction of the ear probe. The wave is reflected repeatedly with lower amplitude each time, as power is dissipated within the system [79]. The sound pressure at the ear probe tip is a superposition of the sound pressure wave generated by the ear probe speaker and the reflected sound pressure wave. If both signal components are of opposite phase, negative interference lowers the sound pressure in this location. This occurs if the distance of travel, i.e. to the tympanic membrane and back, for the sound waves is half the wave length of the signal. Or put differently, if the distance between ear probe and tympanic membrane is a quarter of the wave length. During measurements in adult ears, this usually results in the first quarter-wave null at around $4\,\mathrm{kHz}$. At these locations, sound pressure level differences of up to $20\,\mathrm{dB}$ are possible. However, for frequencies of $2\,\mathrm{kHz}$ and less, the sound pressure in the residual ear canal volume is virtually uniform [159]. Due to the shorter length of the residual ear canal volume when measuring infants, see Table 2.2, the first quarter-wave null usually occurs at frequencies of approximately $8\,\mathrm{kHz}$. This results in an error of $10\,\mathrm{dB}$ or less for frequencies below $6\,\mathrm{kHz}$ [152].

Sound Pressure Level-based Calibration

To compensate the variability of the residual ear canal volume's acoustical properties between each ear probe insertion, several calibration methods have been devised. The direct method is the sound pressure level-based calibration, where the strategy is to set the stimulus amplitude, such that the desired sound pressure level is measured at the probe microphone. This assumes that the sound pressure in the ear canal is almost uniform. As previously discussed, this is not the case for frequencies beyond $2\,\mathrm{kHz}$. The resulting error will mostly affect DPOAE measurements at high frequencies.

The in-ear calibration is based on a frequency response measurement of the ear canal. After ear probe insertion, before the actual OAE measurement starts, a broadband stimulus signal $U_{stimulus,IEC}$ is output by the ear probe speaker into the ear canal. The resulting response $U_{mic,IEC}$ is recorded by the ear probe microphone. Using the earlier obtained microphone sensitivity calibration S_{mic}, the sensitivity of the ear canal sound pressure S_{IEC} as received by the ear probe microphone can be obtained by

$$S_{IEC}(f) = \frac{U_{mic,IEC}}{U_{stimulus,IEC}} \cdot S_{mic}. \tag{2.8}$$

Figure 2.13 shows an example recording with a linear-chirp as stimulus signal $U_{stimulus,IEC}$. The resulting ear canal sensitivity can then directly be used to obtain the necessary (digital) signal output level $U_{stimulus,L}$ of the output for a given desired sound pressure level L:

$$U_{stimulus,L}(f) = \frac{L}{S_{IEC}(f)}. \tag{2.9}$$

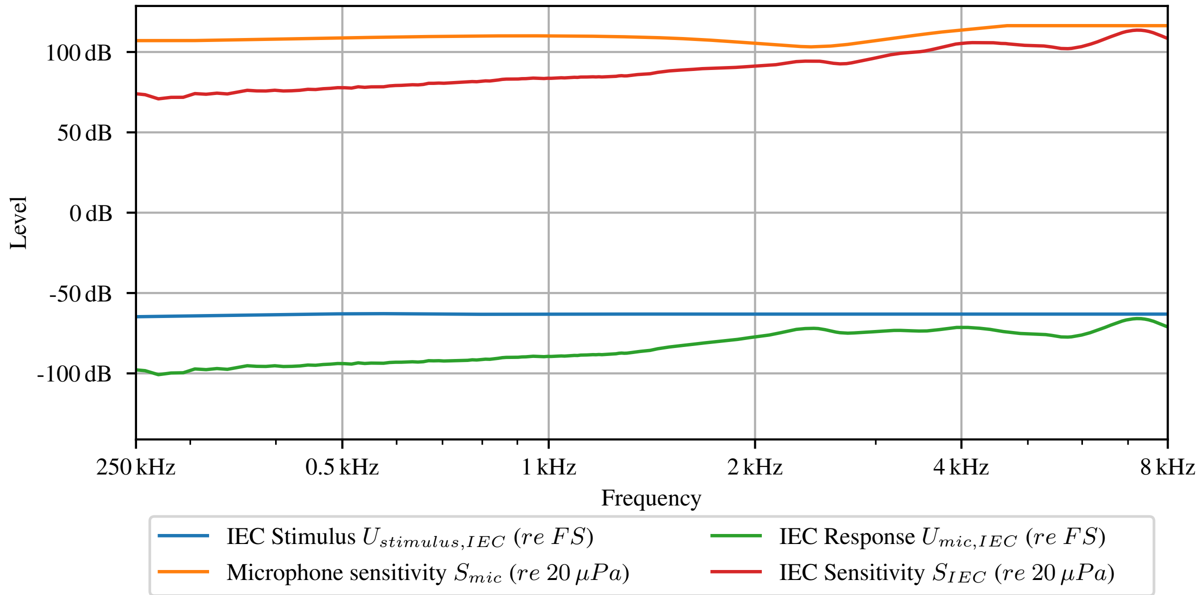


Figure 2.13: Example of a sound pressure-based in-ear calibration. A linear-chirp signal $U_{stimulus,IEC}$ is output using the DAC and the response $U_{mic,IEC}$ recorded with the ADC. Using the previously obtained probe microphone sensitivity S_{mic}, the sensitivity of the ear canal S_{IEC} can be obtained according to Formula 2.8.

For example, using the data from Figure 2.13, if a pure tone sine wave in the ear canal at frequency $f = 1\,\mathrm{kHz}$ and level $L = 50\,\mathrm{dB\,SPL}$ is desired, the output amplitude needs to be $-33.7\,\mathrm{dB\,FS}$.

For DPOAE ear probes, this procedure should be repeated for both stimulus speakers. The resulting IEC sensitivity for each speaker can then be compared. If larger differences are found, this can indicate a blockage of a speaker channel. The IEC sensitivity can be analyzed further to obtain some basic information on the probe placement, as outlined in Section 2.4.5.

This method of in-ear calibration is used for most DPOAE measurements in this work. After obtaining the IEC sensitivity, all tone levels for subsequent DPOAE measurements can precomputed. This allows a non-interactive measurement setup, as is used in Chapter 4.

In-ear Calibration Stimulus

The IEC stimulus waveform amplitude should be chosen, such that all relevant frequencies are excited and the response amplitude is significantly above the noise floor. However, the amplitude must be low enough to not exceed comfort levels in the subjects hearing and such that the distortion introduced by the measurement system, i.e. the amplifiers and speakers, does distort the recorded IEC sensitivity. At lower amplitudes, the waveform can be repeated multiple times and the recording averaged until a certain noise floor is achieved, similar to an OAE measurement.

The IEC stimulus waveform is not limited to linear-chirps. A transient, i.e. click, waveform can also be used. However, since the signal energy must be delivered in a short duration pulse, the introduced distortions usually result in higher errors when calculating primary tone levels for

DPOAE measurements. These level deviations are less of a problem for TEOAE measurements. Additionally, since the TEOAE stimulus waveform is already a broadband signal, it can also be analyzed similar to a dedicated IEC response measurement.

Other Algorithms for In-ear Calibration

The measurement of sound pressures, as described above, is a direct approach to setting the stimulus levels. As discussed earlier, this approach suffers from standing wave interference, which leads to a non-uniform sound pressure distribution in the ear canal. This well known problem has led to a multitude of possible in-ear calibration procedures with individually varying performances [158].

A common approach is applying Thévenin's theorem to the acoustic system, similar to how it is used for linear electrical networks [77], [122], [147]. If the acoustic impedance of the OAE ear probe and the ear canal is known, the sound pressure can be calculated accordingly. The acoustic source impedance of the OAE ear probe can be calculated from measurements with known acoustic loads, usually a series of known cavities. Once the OAE ear probe is inserted into the ear canal, the broadband frequency response is measured once more. With the known acoustic source impedance, the impedance of the acoustic sink can be estimated. Based on the results, the forward pressure level (FPL), the sound pressure component acting on the tympanic membrane, or sound intensity level (SIL), can be calculated. Differences between test performance and between the calibration methods, at least at frequencies below $4\,\mathrm{kHz}$ to $6\,\mathrm{kHz}$, have not been found to be significant [25], [143], [147].

Other approaches include estimating the residual ear canal volume or insertion depths, to adjust the output levels [52], [101], [128]. Finally, similar to estimating the FPL, it was proposed to introduce an emitted pressure level (EPL) as a measure of the actually emitted DPOAE sound pressure, as if no reflection in the ear canal was present [28]. Such EPL estimate might be useful to further improve comparison of DPOAE levels between measurements.

The root cause of the standing wave problem is, that the ear probe microphone is not at the same location as the tympanic membrane, to which a specified sound pressure should be applied. One possible solution is to place the probe microphone further into the ear canal. This can either be accomplished by a simple tube [151] or, to assist placement, with an endoscope integrated into the ear probe [39]. Another approach is to measure the vibrations of the tympanic membrane itself, e.g. by using a laser Doppler vibrometer [31]. However, these procedures are very complex and are a contrast to OAE measurement as a simple to use, non-invasive hearing screening method.

2.4.5 Verifying Probe Placement

Using probes inserted into the ear canal for measuring OAEs has several advantages. However, this method has also several drawbacks, one of them being the standing wave problem in the residual ear canal volume. This problem can be solved to a sufficient degree automatically by the measurement system, especially for hearing screening. The other problem lies is the process of inserting and placing the probe in the patients ear canal. As each ear canal is different in size, shape and accessibility (auricle) the examiner needs to "fit" the OAE ear probe to the ear canal by selecting an appropriately sized and formed ear tip. Then, after carefully inserting the

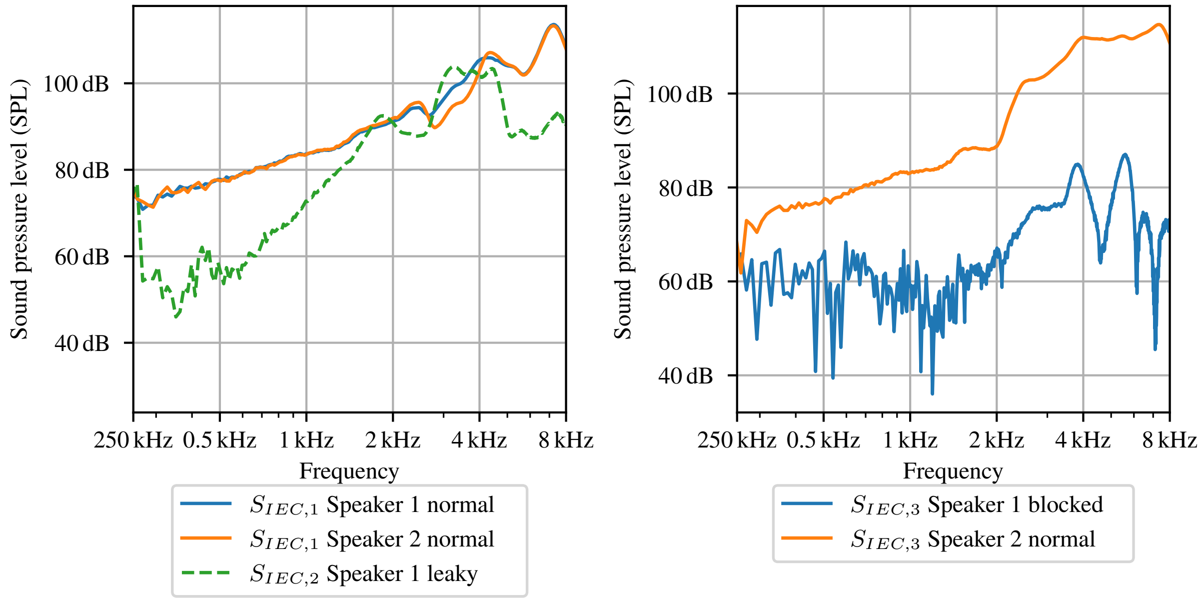


Figure 2.14: IEC response recordings with two speaker DPOAE ear probes. $S_{IEC,1}$: A typical recording, where both speakers exhibit almost the same response. $S_{IEC,2}$: The probe is not sealed properly. Low frequency components are considerably weaker. $S_{IEC,3}$: An asymmetric response, due to one speaker channel being blocked.

prepared OAE ear probe, the measurement can only succeed, if all transducers are connected to the residual ear canal volume without blockage. Blockage might occur due to cerumen or debris in the ear canal, or because a transducer channel faces against the ear canal wall. Additionally, the ear canal must be sealed against the environment, so that external noise is attenuated and OAE sound energy is contained in the residual ear canal volume. Both problems, blockage and leaky probe fit, can be hard to identify externally, especially by inexperienced examiners.

However, some of the probe placement issues can be identified by the measurement system, by analyzing the IEC response recorded by the OAE ear probe [84]. Figure 2.14 shows examples of such recordings. $S_{IEC,1}$ shows a well-formed response, where both speakers of the probe deliver approximately the same sound pressure when stimulated with the same broadband waveform. The response $S_{IEC,2}$ shows a faulty seal of the ear canal. Low frequency components of the response are attenuated. The detection of such a leaky probe fit could be based on the overall signal power measured in the response below a few hundred Hertz. In $S_{IEC,3}$, one of the speaker channels was blocked, leading to an asymmetric response. Detection criteria could be based on the signal power of the difference of both speaker responses. A final case, not shown, is the blockage of the microphone channel. This would not necessarily lead to any detection by the above criteria, if the thresholds are not carefully chosen.

2.4.6 Noise and Noise Reduction

Once the OAE ear probe is placed into the ear canal and the stimulus levels are set based on an IEC procedure, the actual OAE measurement can start. The expected sound pressure of

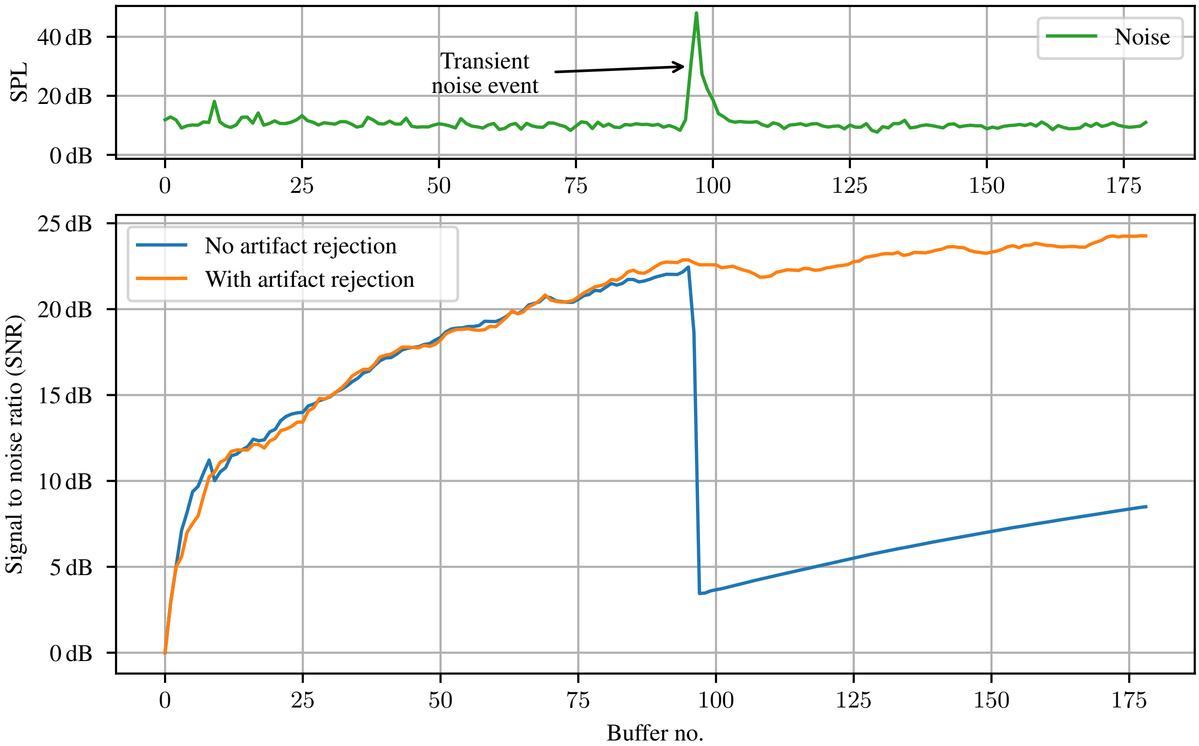


Figure 2.15: Artifact rejection and noise. The upper plot shows the absolute noise level for each buffer in a recording with a transient noise event. The lower plot shows the resulting SNR, if just averaging was applied and if averaging was preceded by an artifact rejection.

the OAEs signal is minuscule at only 10 dB SPL to 20 dB SPL in populations with normal hearing [54]. The OAE signal is usually below the noise level in the ear canal, even after the probe is correctly placed. For a successful detection of OAEs, the noise must be lowered, such that a detection of the signal of interest is possible. In most OAE measurement systems, this is achieved by averaging. Naturally, longer averaging is needed if the noise levels are higher, which means that measurements at low noise levels yield results faster. Since the speed of the measurement is a major benefit of OAEs, especially with neonates and small children, noise is a central problem when measuring OAEs.

Origins of Noise in the Ear Canal

The noise in the ear canal is composed of ambient noise, which originates from the environment, and physiological noise, which originates from the patient.

Ambient noise levels during an OAE measurement vary considerably and can range from 20 dB SPL in a dedicated sound proof chamber for audiological testing, but are often beyond 40 dB SPL to 60 dB SPL in a normal patients room or examination room. (see Table 2.1 for reference). While hearing screening in a sound proof chamber would be preferential, in many situations, the hearing screening must be performed in less than optimal conditions. In those situations, the noise levels are often increased by e.g. air conditioning, personal computers (PCs), outside road traffic and other patients. For neonates, the noise levels at the nursery or neonatal intensive care unit (NICU) might be further elevated. However, ambient noise is not acting directly on the ear probe microphone, but is attenuated by the probe body and the soft ear tip, which cap of the ear canal during the measurement. This attenuation is approximately $10\,\mathrm{dB\,SPL}$ to $20\,\mathrm{dB\,SPL}$ in adults, but less in infants [174].

Physiological noise in the ear canal is the result of the normal activity of the human organism. Sources include the cardiovascular system, breathing, swallowing and jaw movements[175]. Physiological noise strongly occurs an frequencies below $1\,\mathrm{kHz}$ [99]. Noise levels in an unsealed ear canal are around $20\,\mathrm{dB\,SPL}$ [87]. However, the noise level increases, when the ear canal is sealed [80]. Noise levels in ear canals of infants and small children are reported to be even higher [26].

Ear canal noise can be further distinguished into continuous and artifact noises. In the first case, the noise appears as continuous uncorrelated noise, which can be lowered by averaging. The latter case contains transient noises that appear sporadic. Examples are swallowing or closing doors. Both noise classes need to be handled differently for better measurement results.

Averaging

Averaging the recorded data from the ear probe microphone is the primary method to lower the noise of the digital data during an OAE measurement.

If the input processing chain contains a frequency extraction step, i.e. when measuring DPOAE or IEC, the averaging step in the input processing chain can either take place before or after the frequency extraction step. On the one hand, averaging before frequency extraction allows to reduce the execution rate of frequency extraction, which might be helpful during real-time processing in CPU time constrained devices. On the other hand, the amount of data is generally reduced after frequency extraction. When a DFT is used during a DPOAE measurement, only a limited number of frequency bins need to be observed. This might be useful in devices with limited memory resources.

For each input buffer $x_m(n)$ of length N sampled from the ADC, the stimulus buffer (also of length N) is written to the DAC. The stimulus buffer, which does not change during measurement, is then repeated for each subsequent input buffer read. This leads to a synchronous relationship of samples in the input and output buffer, which is constant over the course of the measurement. This also implies, that the input sample sequence is now periodic to the stimulus buffer every Nth sample. The resulting input buffers $x_m(n)$ can now be modeled by

$$x_m(n) = x_{signal}(n) + x_{noise,m}(n). \tag{2.10}$$

The signal, which by itself is a superposition of stimulus reflection and the OAE, remains constant for each buffer, while the noise will differ in each buffer. The synchronous setup of input and output sampling is the base for coherent averaging [92] (sometimes referred to as time-synchronous averaging), which requires that the phase of the signal of interest remains constant during averaging process, while the noise is uncorrelated and mean free. The average of M buffers can then be obtained by

$$\bar{x}(n) = \frac{1}{M}\sum_{m=1}^{M} x_m(n). \tag{2.11}$$

The resulting $\bar{x}(n)$ now contains the original signal and the attenuated noise

$$\bar{x}(n) = x_{signal}(n) + x_{noise,avg}(n). \tag{2.12}$$

If in each buffer $x_{noise,m}(n)$ the standard deviation of the noise $\sigma_{noise,m}$ is constant, it has been shown [34], that the noise in the averaged buffer is

$$\sigma_{noise,avg} = \frac{1}{\sqrt{M}} \cdot \sigma_{noise,m}. \tag{2.13}$$

When comparing sound pressure levels, this results in an attenuation of noise by $-3\,\mathrm{dB}$ each time the number of recorded buffers M is doubled. Or, put the other way, the measurement time can be halved, if the initial noise level is $3\,\mathrm{dB}$ lower. This highlights the importance of a low noise measurement system and ideally a low noise environment.

The reduction, as described in Equation 2.13, can be observed in experimentally obtained OAE data [91]. Figure 2.17 shows a slice of a DPOAE recording after DFT. It can be seen, that the DPOAE response is below the noise floor if a single input buffer is observed. Only after averaging will the noise floor be low enough for the DPOAE response to become visible.

Figure 2.15 shows an example, where the estimated noise level after averaging is shown as each buffer is recorded. However, simple averaging is not effective for transient noise. A single buffer with transient noise that gets included into the averaging, in an otherwise low noise recording, can raise the noise floor to unrecoverable levels.

Artifact Rejection

OAE measurements are often disturbed by short duration noises. Transient ambient noises include closing doors, car horns and sounds of the ear probe cable moving against the patients clothing. Physiological noise source are coughing, swallowing or jaw movement. All these noises have in common, that they are of fairly high amplitude and short duration. The fundamental approach of artifact rejection is to suppress input buffers, that are contaminated with these transient noises. A common approach is to extend the averaging (Equation 2.11) with a weighting factor w_m for each input buffer

$$\bar{x}_{weighted}(n) = \frac{\sum_{m=1}^{M} w_m \cdot x_m(n)}{\sum_{m=1}^{M} w_m}. \tag{2.14}$$

This allows to attenuate buffers with high noise levels, by assigning a small weight. Buffers without increased noise levels can be assigned a higher weight.

Assignment of weights can follow many strategies. Usually, the calculations are based on an estimation of the noise level in the respective buffer. A basic strategy is to reject all buffers that exceed a certain noise threshold, by assigning zero to the respective weights and one to all others. This strategy is shown in Figure 2.15, where buffers that exceed a threshold are effectively discarded. Even for the transient noise event at the 90th buffer the noise level produced by the running average can almost be preserved.

Table 2.3: Stopping conditions for an OAE screening device.

Condition	Result
SNR exceeds threshold	“pass”
Maximum measurement time exceeded	“refer”
Noise level in averaging buffer below a lower threshold	“refer”
Noise level in averaging buffer exceed a upper threshold	“noisy”
Stability score below threshold	“unstable”

Noise Estimation and Deciding

During an ongoing OAE measurement the recorded input samples are sequentially processed in buffers of fixed length. The processing continues, until conditions are met, that halt the input processing, as summarized by Table 2.3. Whichever of these conditions are met first, halts the measurement. To compute most of these conditions, an estimate of the noise and signal levels need to be obtained. These estimates are dependent on the measurement type and are described in Section 2.4.8 for DPOAE and Section 2.4.7 for TEOAE, respectively. In both cases it should be noted, that not only signal and noise need to be separated, but also the reflections of the stimulus signal are present in the input data. Different strategies are incorporated for the DPOAE and TEOAE measurement protocols.

Lowering Noise With Additional Hardware

Noise reduction based on signal processing is limited to the samples arriving from the ear probe microphone. By adding additional hardware components to the measurement system, the noise reduction can be accelerated, either by collecting more entropy, or by lowering external noise.

The noise measured by the microphone can be lowered by combining the outputs of multiple microphones. If N_{mic} equal microphones with a noise level of σ_{single} each are used in parallel, the resulting noise $\sigma_{multiple}$ is lowered by

$$\sigma_{multiple} = \frac{1}{\sqrt{N_{mic}}} \cdot \sigma_{single}. \tag{2.15}$$

The noise reduction achieved by using two microphones instead of one, is the same as doubling the measurement time (see Equation 2.13). This approach was used in the Etymotic Research ER10C OAE ear probe[43], [71], which results in a noise reduction of $3\,\mathrm{dB}$ [174].

In many situations, the ambient noise levels are too high and disturb especially TEOAE measurement. This leads to the idea of additional microphones being used as ambient noise only microphones. Delgado et al. used adaptive filtering of an external microphone to lower noise levels in the ear probe microphone signal [36]. A similar setup was chosen by Kompis et al., who developed a noise reduction system that can be used in line with an existing OAE measurement system [89], [118].

Another approach was taken by Subotić et al., where a second reference microphone was used in the opposite ear [161]. Some of the noise, especially physiological noise like breathing, is correlated between the two microphones. An adaptive filter is then used to estimate a noise

Table 2.4: Selected minimum required functionality of OAE measurement equipment, according to IEC 60645-6.

	Diagnostic device	Screening device
Automatic test	✔	✔
Manual test	✔	
Displayed results	detailed/graphical	"pass" or "refer"
Patient data storage	✔	
DPOAE frequency range	0.5 to $8\,\mathrm{kHz}$	1 to $4\,\mathrm{kHz}$
DPOAE stimulus level	0 to $70\,\mathrm{dB\,SPL}$	50 to $65\,\mathrm{dB\,SPL}$
TEOAE frequency range	0.5 to $4\,\mathrm{kHz}$	1.5 to $3\,\mathrm{kHz}$
TEOAE stimulus level	30 to $90\,\mathrm{dB\,peSPL}$	60 to $80\,\mathrm{dB\,peSPL}$
Measurement range/accuracy	-20 to $30\,\mathrm{dB\,SPL}$ $\pm 3\,\mathrm{dB}$	

signal which gets subtracted from the actual ear probe microphone signal. A drawback of this approach is, that an additional ear probe needs to be placed during the measurement, thus complicating the measurement setup.

Finally, Yates demonstrated an OAE ear probe with a noise only microphone integrated into the probe housing [184]. This arrangement requires a more complex probe but offers a better correlation of the ambient noise microphone signal with the ear probe microphone signal.

In all works with noise only microphones, compared to a conventional measurement system, the SNR improvement is best at increased ambient noise levels. If the measurement is taken at optimal ambient noise conditions, only little improvement was achieved. However, noisy environments, as they are common in many practical situations, usually obstruct the successful measurement of OAEs. This is especially a concern with the TEOAE protocol, which is more sensitive to noise and very popular for hearing screening.

2.4.7 Measuring TEOAE

Section 2.3.3 describes how a click stimulus excites OAEs in the auditory system. This sections discusses the actual TEOAE measurement procedure for hearing screening applications.

The stimulus click (or transient) is usually a $80\,\mu\mathrm{s}$ to $200\,\mu\mathrm{s}$ impulse of the ear probe speaker. To quantify the resulting sound pressure amplitude of this short duration stimulus, the usage of peak-equivalent SPL (peSPL) is common [100]. Typical levels for stimulation in screening applications are $70\,\mathrm{dB\,peSPL}$ to $80\,\mathrm{dB\,peSPL}$. Small differences in absolute stimulus level have only a minor impact on the recorded response. Higher stimulus levels generally excite a stronger response [83]. The stimulus levels can be observed during an ongoing TEOAE measurement, using the ear probe microphone, to estimate the current peSPL. Based on the reading, the stimulus level may be adjusted. However, even if the stimulus is set to a constant level, the difference in stimulation sound pressure between adult subjects is only $4\,\mathrm{dB}$ [84]. While click-based TEOAEs are well suited for the detection of sensorineural hearing loss (SNHL), other stimulus shapes may also be used [105].

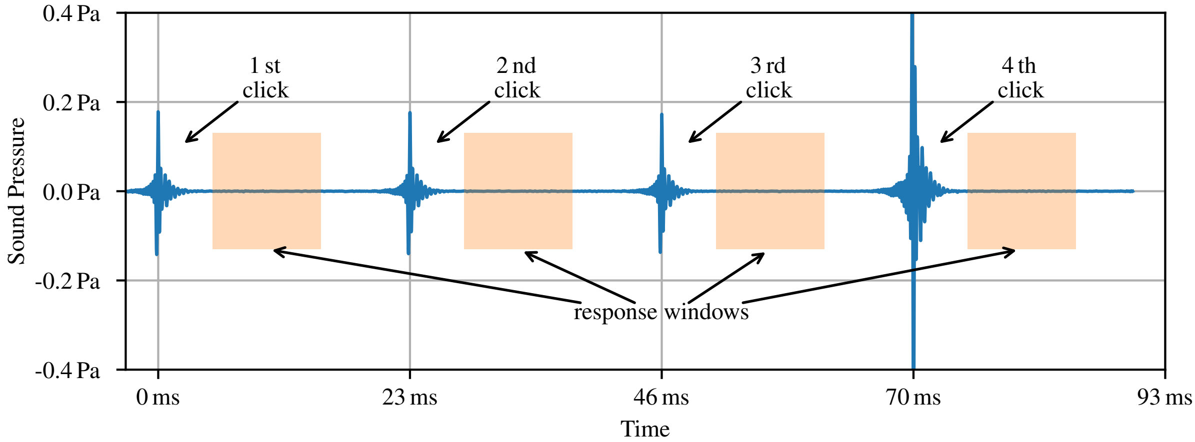


Figure 2.16: Click sequence of a TEOAE measurement. Three equal clicks are followed by a fourth click with inverted polarity and three times the amplitude. By averaging all four response windows, the linear components are canceled out.

Immediately after the click was output by the speaker in the ear probe, the stimulus and reverberations of the stimulus, are recorded by the ear probe microphone. The reverberations occur very shortly after the stimulus itself. At the same time, the highest frequency components of the OAE response, which are processed at the base of the cochlea, arrive at the ear canal. This early OAE response, which is approximately $60\,\mathrm{dB}$ to $80\,\mathrm{dB}$ weaker than the stimulus reverberations, cannot be separated from each other. The issue of the stimulus overlapping with the OAE response can be lessened by using the *non-linear protocol* [83], [84]. Figure 2.16 shows the basic principle. Three stimulus clicks of normal amplitude are followed by a fourth inverted click with three times the amplitude. Each normal amplitude click will excite an OAE response and other linear signal components. After the fourth click, these linear components appear at three times the amplitude. However, the non-linear OAEs will not grow linearly. By averaging each click response, the linear components are virtually canceled and only the non-linear TEOAEs remain (as well as random noise).

To further lower the noise, the click-sequence is repeated continuously. The next click can follow immediately after the recording window of the preceding click. To further lower artifacts in the recorded response, the recorded signal is band-pass filtered, e.g. with an finite impulse response (FIR) filter. After filtering, artifact rejection and averaging is used, as described in Section 2.4.6. The averaged signal is then analyzed in a fixed time window after the stimulus, which contains OAEs in a window of up to $20\,\mathrm{ms}$. However, for hearing screening and the detection of hearing loss, a window size of $13\,\mathrm{ms}$ is sufficient [173]. A smaller window results in a higher click rate and thus more averages in the same total amount of time. This results in a better SNR, which means a faster measurement. The frequency components of the OAE will appear in dependency to the time since stimulus onset. In adults, the $4\,\mathrm{kHz}$ components are strongest after $5\,\mathrm{ms}$ and the $1\,\mathrm{kHz}$ components after $10\,\mathrm{ms}$ [168].

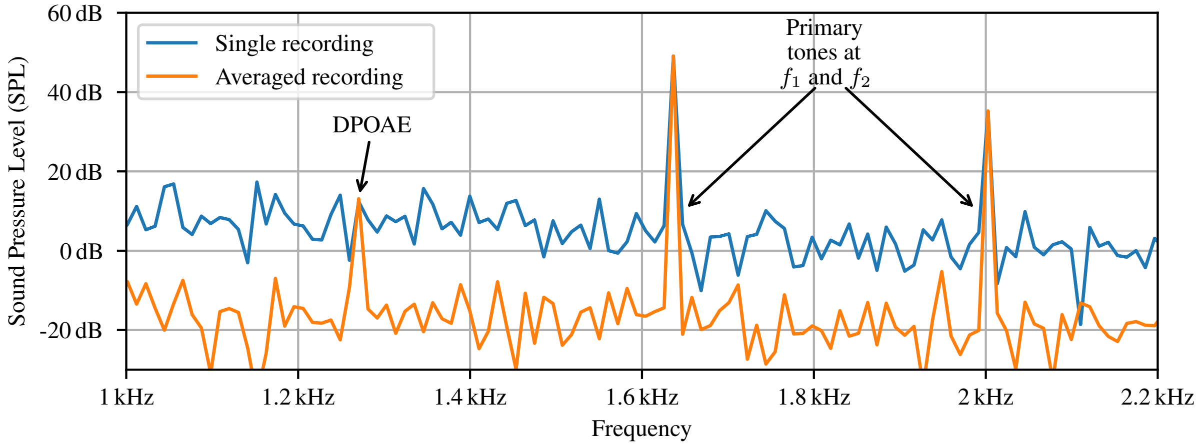


Figure 2.17: Example of a DPOAE recording at $2\,\mathrm{kHz}$. The OAE response has an amplitude of $13\,\mathrm{dB\,SPL}$ and the noise floor is at $-15\,\mathrm{dB\,SPL}$.

2.4.8 Measuring DPOAE

Section 2.3.4 introduced DPOAEs and their physiological origin. In this section, the excitation and measurement of DPOAEs in the context of hearing screening is discussed. The stimulus consists of two sine waves (primary tones) of frequency f_1 and f_2 with a sound pressure level of L_1 and L_2 respectively. These primary tones can be described by four characteristics (a) absolute frequency, (b) frequency ratio f_1/f_2, (c) absolute level and (d) level difference between L_1 and L_2. The selection of these parameters aims to evoke a robust DPOAE response from which meaningful conclusions on the state of the auditory system can be drawn.

The absolute frequency of the primary tones is given in terms of f_2, since the primary source of the DPOAE is close to the characteristic region of f_2 [85], [94]. The diagnostically most effective region is in the range of $2000\,\mathrm{Hz}$ to $8000\,\mathrm{Hz}$ [55]. Frequencies below $1000\,\mathrm{Hz}$ yield less reliable results due to the increased noise floor at low frequencies [16], [57]. Highest accuracy in detecting hearing loss is usually achieved by testing a mid to high frequency range. The optimal frequency ratio of f_2/f_1 is on average 1.2 for adults as well as newborns. At this ratio the most robust DPOAE response can be produced [1], [49], [58]. However, the optimal ratio varies slightly between each subject and with stimulus level and stimulus frequency.

The OAE response grows with the primary tone levels [37], [133]. Moderate primary tone levels of $55\,\mathrm{dB\,SPL}$ to $65\,\mathrm{dB\,SPL}$ yield the best result for the detection of hearing loss [160]. L_1 should be higher than L_2 for hearing screening at typical primary tone levels [1], [49]. For best results, the difference rises with lower L_2 stimulation levels. Suitable tone levels for most screening applications can be set by using the "scissor paradigm" $L_1 = 0.4 \cdot L_2 + 42\,\mathrm{dB\,SPL}$ [95], [96]. Other methods for obtaining the optimal primary tones levels have also been proposed, including the use of primary tone frequency as a parameter [73], [88].

Independent of how the "optimal" primary tone levels are selected, they represent the sound pressure that should act on the tympanic membrane. To set these levels correctly and to improve reproducibility between measurements, the levels must be set using an IEC procedure after insertion of the ear probe, as described in Section 2.4.4. The stimulus and response sampling is based on buffers of fixed length. To improve and simplify the analysis of the obtained response recording, the frequency of the primary tones sine waves is set, such that one stimulus buffer of fixed length will always contain an integer number of oscillations. This fixed length stimulus buffers can now be repeated by the measurement system without discontinuities in the resulting acoustic signal. This results in the primary tones being captured in the recording without discontinuities between buffers, while still simply repeating the same constant stimulus buffer. When a DFT is applied to the recorded response buffer, all stimulus frequencies are centered exactly in their respective bin. Additionally, due to the strict arithmetic relationship between the DPOAE frequency and the primary tone frequencies, the DPOAE signal is also centered exactly in a DFT bin. In this case, no windowing is needed before applying a DFT, since no frequency leakage occurs [176]. At the same time, synchronous averaging, as described in Section 2.4.2, can now be used without interference of non-periodic frequency components (except the noise). Finally, since DPOAEs are based on IMD, care must be taken, that no other significant IMD sources are present in the measurement setup. For example, IMDs can be generated by speakers, such as in the ear probe, if they are stimulated with two sine waves of different frequencies. Since the source of the IMD would not easily be distinguishable in the recorded signal, DPOAE ear probes have two independent speakers. Each speaker is used to output one of the primary stimulus tone.

Noise reduction and averaging is analogous to the principles in Section 2.4.6. After the obtained averaged signal is frequency transformed, e.g. by fast Fourier transform (FFT), the noise and signal levels can be estimated. Figure 2.17 shows an example of a recording at $f_2 = 2\,\mathrm{kHz}$. The first is the frequency transformed of the raw recording, which is dominated by the primary tones. The DPOAE signal is still concealed in the noise floor. The second lines shows the recorded response after averaging multiple buffers. The primary tones and DPOAE response remain unaltered after averaging, but the noise floor level is lowered. Measurement and averaging continues until one of the stopping criteria is met, which is either a timeout, a noise floor level or SNR (see Table 2.3). This means, that noise floor level and DPOAE level need to be estimated from the averaged recording. The signal magnitude is usually estimated simply by the amplitude of the DPOAE signal frequency bin. Noise floor can be estimated by averaging surrounding frequency bins. Alternatively, the variance of the frequency bin of the DPOAE signal and surrounding bins can be used. Estimating the noise floor close to the frequency of interest is necessary, since some noise components are frequency dependent and the noise floor increases at lower frequencies. At a threshold SNR of $10\,\mathrm{dB}$ to $15\,\mathrm{dB}$ the signal can be considered significant [13]. However, the exact threshold depends on the used noise estimator and expected variance.

While DPOAEs occur at multiple frequencies, $2f_1 - f_2$ has the most robust amplitude in humans [56]. Absolute DPOAEs levels cannot directly be used to estimate the degree of hearing loss [3]. However, indirect estimations are possible [144]. For hearing screening purposes, two criteria must be met for a DPOAE signal to be considered normal: The SNR must exceed the system specific threshold and the absolute level of the DPOAE signal must be above an age dependent threshold. Since DPOAE responses are more robust in infants, the thresholds must be set higher to lower the false negative rate [2], [16], [135].

Finally, since one DPOAE recording only tests the auditory system at only one particular frequency, the measurement must be repeated multiple times to obtain a meaningful result. Each individual measurement is tested against the SNR and DPOAE signal level threshold. The criteria must be met approximately at $70\,\%$ of collected data points. In practice, this results in an overall "pass" of the measurement if the criteria are met at four to five out of six f_2 frequencies [3].

3
Standalone Low-cost OAE Hearing Screening Device

In this chapter, a hearing screening device is presented, based on low-cost commercial of the shelfs (COTSs) components. First, an analysis of computational offloading in smartphone-based system architectures is discussed. Based on the results, the hardware and software of the a novel standalone device prototype is presented, where the ear probe is integrated into the device body. The device is then equipped with additional sensors to improve usability.

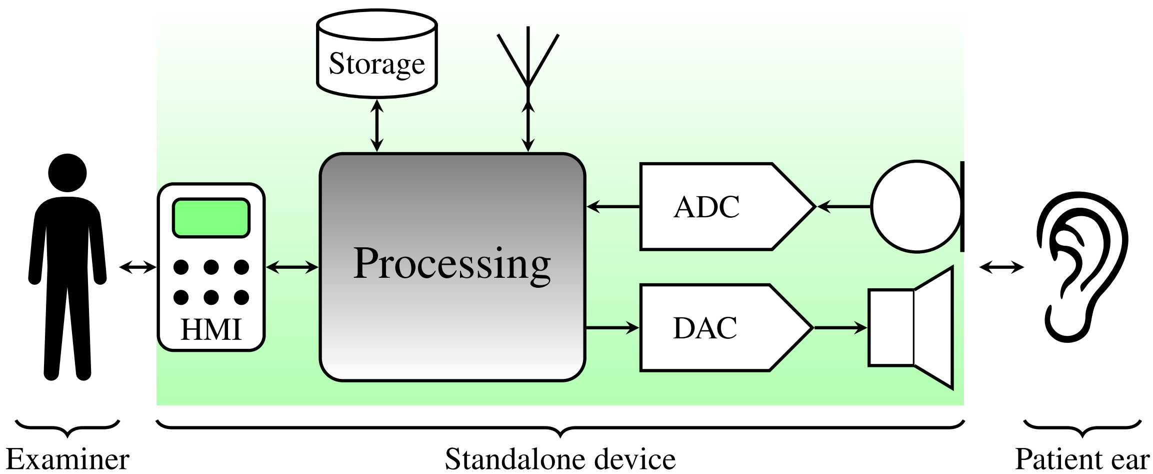


Figure 3.1: Schematic overview of the standalone OAE screening device. To reduce the number of components and the overall complexity, the OAE ear probe has been merged into the device itself.

3.1 Introduction

Hearing impairment is one of the most common forms of disability and is widespread in developing countries like India. Four out of every 1000 children born in India were found to suffer from severe to profound hearing loss, with a larger number being at risk [93]. Since it is largely invisible, especially in its mild to moderate forms, it often remains unnoticed in newborn children and infants for considerable amounts of time. It can have profound consequences – both psychological and physical – and lead to delayed speech and language acquisition and poor cognitive, social and emotional development. However, with appropriate intervention and treatment at the right time, a majority of these cases are curable.

Unfortunately, a study concluded "The concept of early identification and intervention is yet to gain foothold in India. No dedicated national program has been carried out so far in India for early detection of hearing loss in children" [163]. The problem stems from the lack of trained personnel and equipment in many hospitals. However, there is now a growing consciousness and the screening of newborns is slowly gaining momentum in India, although it needs to be implemented more widespread [165]. However, a lot more work needs to be done for the regular screening of children and adults exposed to high levels of noise, particularly in their work environments (e.g., in factories, construction sites or areas with high volumes of traffic). Studies have found that children in rural areas of India suffer more hearing loss than children living in urban areas. A study of 1,670 Indian school children (1030 urban and 640 rural) found hearing loss in $6.3\,\%$ of the urban group, compared to $33\,\%$ in the rural group [109].

It is well understood that regular hearing screening of both children and adults will help with the detection of the onset of hearing impairment. The affected patients may then be referred for treatment early on, thereby significantly improving their chances of recovery or prevent further deterioration. However, in countries like India, the lack of compulsory screening for newborns and regular screening for children and adults stems from (a) the lack of trained personnel (ear, nose, and throat (ENT) specialists and audiologists) who can administer appropriate tests using available screening/testing equipment, and (b) the high cost of currently available equipment, which is only available in selected hospitals and medical centers.

In an effort to target the issues discussed here, the Indian-German Sound4All research project was initiated. This research project is co-funded by the Indian federal Department of Science and Technology (DST) and the German Federal Ministry of Education and Research (BMBF). Part of the project is to investigate hearing screening technology, that has potentially reduced cost, complexity and is easy to use, even by laypersons. This chapter is focused on the investigation of possible hearing screening system architectures. An appropriate solution, the standalone architecture, was selected. A prototype system, based on low-cost COTS components is presented, which serves as a platform for further research of hearing screening solutions.

The remainder of this chapter is structured as follows: Section 3.2 gives a brief overview of hearing screening and otoacoustic emission (OAE) hearing tests. Section 3.3 investigates meaningful system architectures and how smartphones can be integrated. The hardware and software of the standalone device are discussed in Sections 3.4 and 3.5 respectively. In Section 3.6, additional sensors are added, which are used for ear side classification in Section 3.7. This chapter is concluded with the discussion in Section 3.8.

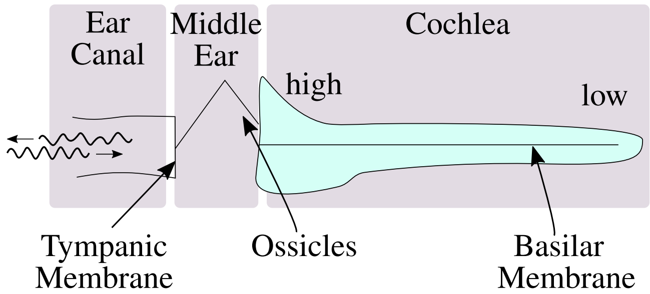


Figure 3.2: Schematic overview of the ear canal, middle ear and cochlea. The cochlea is shown "rolled out".

3.2 Hearing Screening

This section gives a brief introduction to hearing screening from a measurement system point of view to a degree of detail, that is relevant for this chapter. For a more detailed review, the reader is referred to Chapter 2.

Audiology provides a wide set of tools to asses the auditory system, where each has its own advantage and disadvantage and therefore application. In a simplified manner, the goal of each assessment can be split into screening or diagnosis. The objective in screening is to separate those people who have a potential hearing disorder from those who do not. This can be represented as "pass" and "refer" results. Diagnosis on the other hand aims to give a clinician details on the hearing disorder to help identify the underlying disease. This work focuses primarily on screening.

A common hearing screening method is to utilize otoacoustic emissions (OAEs), which are sounds generated by active amplifications processes in the inner ear. One important advantage is, that this is an objective test, which does not rely on the patients' cooperation. This allows fast and efficient screening in wide parts of the population including newborns.

3.2.1 Otoacoustic Emissions

To understand and utilize OAEs, it is important to know how OAEs are stimulated and recorded, and what the surrounding conditions are. This section gives a brief introduction to this topic.

An overview of our hearing organ in shown in Figure 3.2. First, an ear probe is inserted into the ear canal, which contains one to two speakers and a microphone. When inserting the probe into the ear, it is important to have a sealed, but comfortable fit, which is achieved by a soft probe tip material. This poses some challenges in practice, since ear canal shape and diameter are far from uniform and have a wide variation depending on the age (newborn vs. adults). A seal is necessary since the OAE is so weak that every loss of signal energy must be avoided. Also, a tight seal prevents ambient noise from reaching the probe microphone. With the insertion of the probe, a small cavity between probe and ear drum remains. Since this residual ear canal volume is very small, even slight changes in the probe fit will change the acoustic properties. Even reinserting the same probe into the same ear might change them drastically. Nonetheless, it is important to deliver a very specific sound pressure level to the ear drum. This is usually achieved by an in-ear calibration (IEC), in which the sound pressure levels generated by the speakers are determined in situ [152]. In this process, the microphone is used as a reference and is assumed to be representing the sound pressure at the ear drum, which works well for lower frequencies. Blockage of the probe with cerumen and also probe movement during measurement, might change the calibration. Both of these problems may be automatically detected by analyzing the acoustic response of the IEC.

With the stimulus reaching the ear drum, it enters the middle ear. The function of the middle ear is to match the impedance of the sound waves in the air to the liquid filled cochlea. It has a significant impact on the OAEs, since the signal has to travel through it entering the inner ear and traveling out again. In newborns, OAEs are often attenuated due to fluid in the middle ear shortly after birth, which results in a “refer”.

The cochlea is the organ where the sound waves are converted into nerve signals. It is a small spiraled chamber with ducts (*vestibular duct* and *tympanic duct*), which are connected at the apex. The basilar membrane is in between those two ducts and holds the cochlear partition. This in turn includes the organ of corti with the inner hair cells (IHCs) and outer hair cells (OHCs), which can be found in rows on the full length of the membrane. The basilar membrane is stiffer at the base of the cochlea and gets wider and heavier closer to the apex. With this property, sounds of different frequencies are resolved in a spatial manner. The IHC generate the nerve signals, whereas the OHC function as active amplifiers. They are able to amplify, attenuate and improve frequency selectivity. This active process generates the OAEs [82]. There is little evidence that IHC or afferent nerves are involved in OAE generation. The summary given here is a simplification of this complex organ and a more detailed description of the human auditory system, and how OAEs are generated can be found in Section 2.2.

3.2.2 Relation to Other Hearing Screening Procedures

Further procedures in hearing diagnosis include pure tone audiometry, and other objective tools like the otoscope, tympanometry and measuring auditory brainstem response (ABR). In contrast to OAEs, pure tone audiometry and ABR test the whole hearing organ, including the auditory nerve and brain stem. However, pure tone audiometry is a subjective test, as it requires cooperation with the patient and also a low noise environment. ABR is more complex to set up and the patient is not allowed to move. Both methods need much longer measurement time than OAEs. Since most hearing disorders, especially when screening neonates, stem from peripheral hearing, OAEs are a very powerful tool for hearing screening. With some practice, a simple OAE screening can be done in a few seconds per ear, with minimal preparations.

3.3 Preconsiderations

The goal of the work presented in this chapter is a hearing screening device with reduced cost, a focus on increased usability for laypersons and high reliability. Existing audiometry methods shall be used, which aims towards maintaining screening quality. Acceptance and comparability to existing devices is expected to be higher, when an established method is used. For the reasons explained in the previous section, the device will be based on OAEs. This section defines the objectives for such a hearing screening device, and presents an analysis of possible computational offloading scenarios of smartphone-based systems.

Currently available hearing screening devices consist of complex electronics and software, and cost upwards of €1,000 (with a manufacturing cost of approximately €400). Low-cost devices are of interest within several scenarios:

- Devices to be used by organizations such as schools and factories for regular monitoring.
- Devices intended to be bought by individuals for personal use purely for screening.
- Devices to be donated or sponsored by aid/governmental organizations for individual use, particularly in rural areas.

3.3.1 Objectives

Cost Reduction

Existing screening devices use dedicated hardware for processing. In order to reduce hardware costs, the signal processing algorithms could be run on a smartphone, using either wired or wireless links. Even low-cost smartphones currently have very powerful processors that are capable of running complex signal processing algorithms. Further, the usage and penetration of smartphones in India is very high, including rural areas. Even low-end smartphones offer abundant processing power for this application and at a cost of less than € 100. The smartphone technology will advance and their costs will be reduced further in the future. The idea is to exploit this development in order to reduce the cost of OAE hearing screening devices. When a smartphone is used in this context, it still needs to interface the human ear with an OAE ear probe. This requires some hardware and eventually some processing outside of the smartphone. Section 3.3.2 is dedicated to the question, if this separation of processing is useful.

The mentioned proliferation of smartphones has also made electronics components available for other applications, that used to be more expensive and performed worse. These include audio codec integrated circuits (ICs), which convert audio from digital to electrical domain and vice versa, as well as power management integrated circuits (PMICs), battery cells and low-cost/low-power communication solutions. This development in consumer electronics made powerful technology available as COTS components for specialized applications like OAE-based hearing screening.

Ease of Use

The second goal is to have a design which allows even laypersons to conduct the screening. Most commercially available devices show very detailed information, which, for a clinician, are very important and useful, but for untrained users they are neither. In terms of usability, the device has to be simple enough to be used without training, but at the same time must offer help if there are problems.

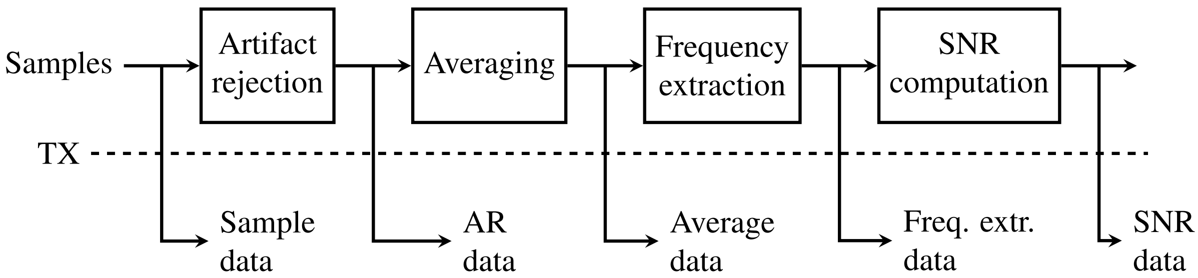


Figure 3.3: Distortion product OAE (DPOAE) input processing chain of the OAE screening reference system used to analyze benefits of computational offloading.

Reliability

Third the device has to be reliable in a technical sense, as well in the medical context. On the one hand, if the device misses a hearing defect (false negative), the patient might not get the treatment that is required. On the other hand, it is possible that a defect is detected, but the patient is healthy (false positive). If this happened too often, the confidence in the device would decrease. However, OAEs are reported to have excellent sensitivity ($> 90\,\%$) [11]. Related to this reliability is, that this device has to operate in harsh conditions. The field of application is not a well equipped audiometry lab, but small clinics and schools with high background noise and other disturbances.

3.3.2 Computational Offloading and Partitioning

In this section, the costs and benefits of computational offloading are explored. When devising an OAE hearing screening system, a multitude of design choices needs to be made. Integrating a smartphone as part of such system further increases the degrees of freedom. The integration of a smartphone offers by itself multiple possible implementation choices:

Partitioning of the algorithm Most of the signal processing in an OAE screening system is dedicated to the ear probe microphone input. A simplified processing chain, as it will be considered in the remainder of this section, can be seen in Figure 3.3. The system might be divided at any signal processing block, before sending the data to the smartphone, where the remainder of the processing is executed. Early extraction of the data from the device requires a higher bandwidth, but lowers the computing requirements, e.g. central processing unit (CPU) utilization, in the device. If the data is extracted at a later stage, more processing needs to be done on the device, but with less bandwidth needed.

Connection technology Smartphones offer a wide selection of communication possibilities. These include Wi-Fi, Bluetooth, Bluetooth low energy (BLE), near field communication (NFC) and universal serial bus (USB). Additionally, digital information can also be transferred using the camera (e.g. Quick Response (QR) codes) or even the microphone input. Each choice comes with its own limitations and advantages, as each technology will have its own bandwidth limitations, energy demand and costs per unit. Selection of the connection technology and partitioning of the algorithm must be considered together. Ease of use of a technology might also be considered, e.g. pairing and connecting Bluetooth devices requires additional steps, compared to NFC.

Power Depending on the amount of processing executed on the device and the chosen connection technology, the OAE measurement system will have a characteristic energy consumption. Powering the device, e.g. by a battery, will impact the per unit cost, but also the physical size of the device. Certain connections technologies, e.g. USB, are able to deliver power to the measurement system and make an additional power source obsolete.

Partitioning Reference System

An OAE reference measurement system was set up to systematically explore the possible design choices. This work was part of a Master's thesis by Hernangómez [66], which was executed in the context of this work. The remainder of this section presents data collected during his work and highlights important results and conclusions.

A typical measurement system, as can be seen in Figure 2.9, was set up. A pre-existing commercially available OAE ear probe was connected to an audio codec IC (NXP SGTL5000), which provided analog-to-digital converter (ADC) and digital-to-analog converter (DAC) functionality, as well as the necessary amplifiers. The processing was implemented by an ARM Cortex-M4F-based Silicon Labs EFM32WG990F256 microcontroller unit (MCU), which runs at $48\,\mathrm{MHz}$ and has $32\,\mathrm{KiB}$ of random access memory (RAM). The MCU and audio codec IC were connected by an Inter-IC Sound (I²S) peripheral bus. USB was used as data connection to the host system.

The processing chain shown in 3.3, which provides all functionality necessary for a simple DPOAE hearing screening system, was implemented along with the necessary low level drivers on the MCU. Direct memory access (DMA) operations on the peripherals and memory were used whenever possible by the interrupt driven software. As a result, the sampling does not require any significant CPU time, neither on output nor on input. Processing of the input is done in buffers of fixed length, which are processed once they are filled. The firmware was setup reconfigurable, such that any of the intermediate buffers can be transferred to the host, where the remaining processing steps are completed. The five possible extraction configurations, as can be seen in Figure 3.3, are referred to as partitions of the algorithm:

Sample data The data is read from the peripheral of the MCU by a DMA. After a sample buffer is available, it is sent to the host without any processing.

AR Data An artifact rejection (AR) algorithm identifies unusually noisy buffers and discards buffers, which are past a threshold, before sending them to the host.

Average data The average is calculated as a cumulative moving average (CMA), such that only a single averaging buffer is needed and the averaging result is always scaled uniformly, when it is sent to the host.

Frequency extraction data The discrete Fourier transform (DFT) bins of the DPOAE frequency and four surrounding bins are calculated using the Goertzel algorithm [127]. The magnitudes of these five values are sent to the host.

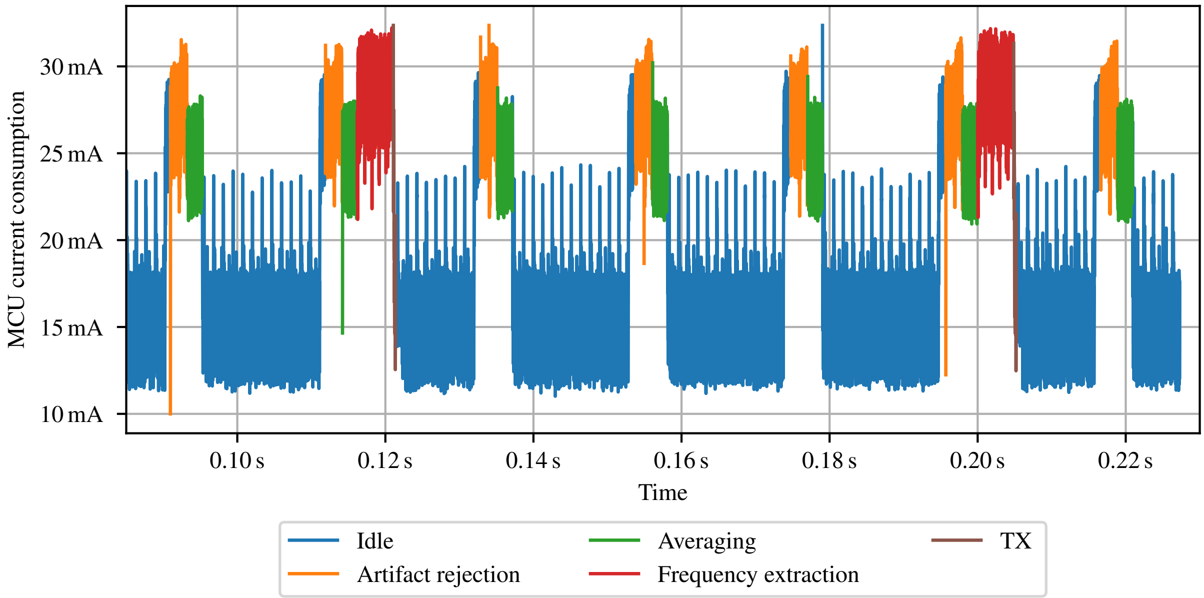


Figure 3.4: Measured current consumption of the OAE screening reference system using the "frequency extraction" partition, during which the DFT results are calculated and transmitted via USB every fourth buffer.

SNR Data By comparing the frequency bin of the DPOAE to the surrounding bins, a single signal to noise ratio (SNR) value is calculated, which is then sent to the host.

Due to the limited RAM in such small embedded systems, all incoming buffers need to be processed almost immediately, to avoid an overflow. However, after the average data is calculated, the following steps and the final SNR result can be executed at a reduced rate, which is referred to as extraction rate.

To attribute the CPU time and current consumption during the experiments, additional general-purpose input/output (GPIO) pins were used to signal the current active processing block with minimal overhead. An external measurement device was used to sample these GPIO pins and the current consumption.

An example current consumption measurement, with each input processing block labeled, can be seen in Figure 3.4. In this example, the input buffer length was 512 samples and the sampling rate was $24\,\mathrm{kHz}$. The extraction rate was set to four, i.e. the frequency extraction was executed every fourth buffer. The resulting frequency extraction data was then sent to the host system over USB. The CPU was put into sleep mode during the idle periods, which is reflected by the lower current consumption. However, the peripherals, e.g. I²S, DMA, and USB, needed to stay active, which increased the idle current significantly. During all system states, be it idle or active, the DMA, which read samples from and wrote samples to the I²S peripheral, needed updating every few ms. This was done from the corresponding interrupt service routine (ISR) context. This behavior is visible in the plot during the idle periods as the large ripple spikes.

The measurements were repeated in different configurations of buffer length, sampling rate, sample word size. Additionally all five partitioning schemes were tested.

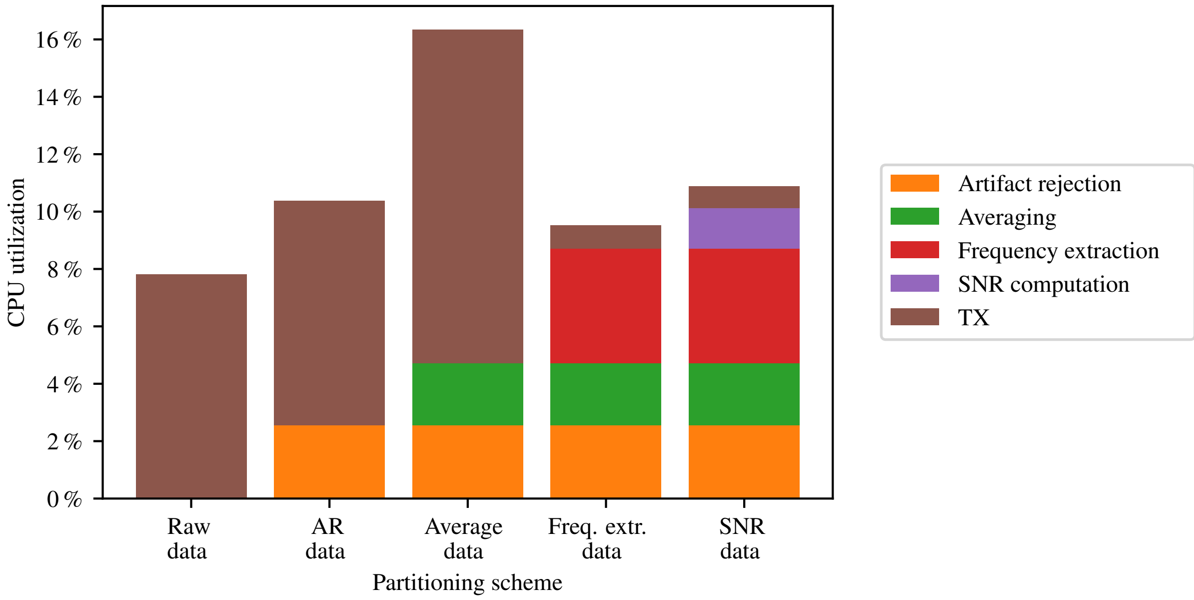


Figure 3.5: The CPU utilization of the OAE screening reference system with the five different partitioning schemes, as shown in Figure 3.3

Measurement Results

Figure 3.5 shows the CPU utilization of the average configuration for each processing block and each partitioning scheme. The CPU time for transmission (TX) over USB is particularly high on this specific system, since some busy waits are present. However the CPU time spent scales with the bandwidth used for data transmission. As expected, more CPU time is needed on the reference system, when more of the input processing chain is executed. Even with only five frequency bins, the frequency extraction step has the highest CPU time share of all computational parts.

Energy saving on the reference system could mostly be achieved by lowering the system clock speed, since critical peripherals need to be running continuously and cannot be turned off during idle. Additional to the MCU power consumption, the power consumption of the audio codec IC was also measured on all configurations. However no significant correlation between the power consumption and sample word size or sampling rate was found for the audio codec IC.

Even on the resource limited embedded platform of the reference system, the CPU utilization was below $20\,\%$. On one hand this indicates, that the processing could be much more complex in an actual system, when executed on the same hardware. On the other hand, the system might be implemented on an even lower-cost hardware. Further, the signal processing in this work was implemented with floating point operations. However, all steps can be almost equivalently implemented with fixed point operations. This speeds up execution and requires less computing resources.

Implications

In conclusion, if no bandwidth limitations of the connections technology is present, e.g. when using USB, it is most advantageous to not process the data and sent the raw sample data directly to the host. This is the equivalent to a sound card, for which dedicated audio codec ICs with USB interface exist. This probably leads to the lowest-cost smartphone-based solution, since an external MCU is not required.

If the bandwidth is limited, e.g. when using BLE, data should be extracted after averaging. By lowering the extraction rate, the resulting bandwidth requirements can be arbitrarily low. The extreme case is, that only a single average buffer is transmitted after the measurement is concluded after a fixed time. The main drawback is, that no intermediate results can be displayed to the user and that the measurement can not stop early if an OAE signal was found.

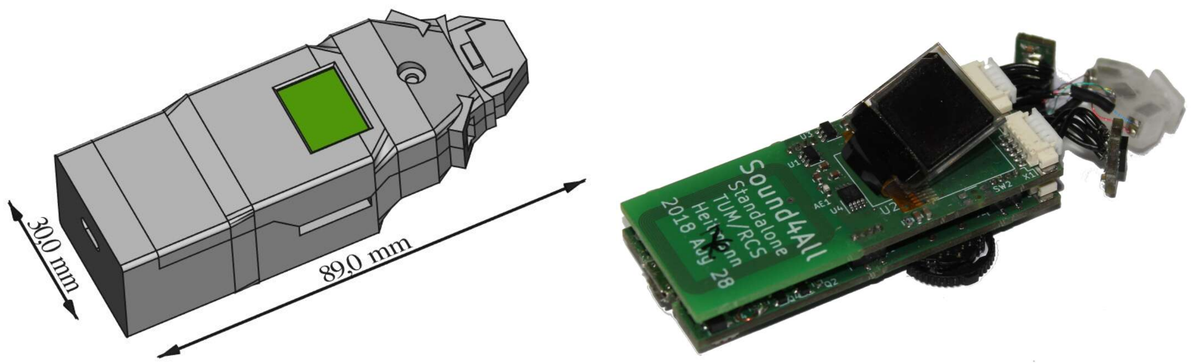
Running the full processing chain on the screening device has the highest CPU time increase, when the extraction rate stays constant. The same argument for lowering bandwidth of the average data by decreasing the extraction rate can be applied to the CPU time demand of the frequency extraction and SNR steps. Both steps need only a few words of RAM and can thus be almost always be implemented on the screening device itself by selecting a low extraction rate. After the measurement is completed, it is still possible to transfer the average data to the host. This might be useful for detailed measurement reports, especially when measuring transient evoked OAEs (TEOAEs). Since the measurement itself is completed once this additional data is transmitted, the data can be transported even over a low bandwidth connection since real-time is not required anymore.

3.3.3 Conclusion

Using a smartphone as part of an OAE hearing screening system opens up many design choices. However, after systematic exploration, only a subset of systems partitions stand out as sensible. The lowest-cost approach appears to be one, where no processing is done on the screening device. Chapter 4 follows this approach further, where the smartphone is used as the screening device itself and the only external component is the OAE ear probe.

However, with the results of the partitioning experiments and the context of the Sound4All research project, it was decided to follow a standalone device approach. As the reference measurement systems shows, the components needed directly for OAE hearing screening, i.e. processing, ADC and DAC, are low-cost components. This results in little benefit of computational offloading in this particular application. However, other benefits of a smartphone as part of such systems still remain: The smartphone offers an excellent user interface, which can often be intuitively understood, large amount of permanent storage for patient data and network connectivity to integrate into clinical data management systems (CDMSs) or telemedicine.

Smartphone supported OAE screening devices already exist. For most products, the smartphone is used for patient data management and similar tasks. A notable exception is the Neurosoft aScreen [8], which is fully remote controlled by an Android smartphone. All devices have in common, that the probe is connected via a cable. The novelty of the standalone device discussed in the remainder of this chapter is, that the OAE ear probe is merged into the device itself. Figure 3.1 gives an overview of the proposed architecture. The device is intended to be



(a) 3D render of the CAD model of the enclosure.

(b) Photograph of the PCB stack and external components, excluding the battery.

Figure 3.6: Pictures of the standalone OAE screening device.

used similar to an in-ear infrared (IR) fever thermometer. The device proposed here is intended as a research platform to explore aspects of low-cost screening devices, including usability. Consequently, the standalone device is primarily designed to easily facilitate modifications and additions to allow experiments in the discussed areas.

Next, the design of the standalone device hardware and software are presented in Section 3.4 and Section 3.5 respectively.

3.4 Hardware

Following the conclusion of the last section, the a standalone OAE hearing screening device was designed. To lower part count, reduce complexity and assembly time the OAE ear probe is merged into one device. This design is intended to be used similarly to an in-ear IR fever thermometer. The system overview can bee seen in Figure 3.1.

3.4.1 Mechanical

All components of the standalone OAE screening device, including the ear probe, are contained in one enclosure. One end of the enclosure forms the ear probe body. To simplify assembly, as many hardware components as possible were placed on the printed circuit boards (PCBs). As a result, all electronic hardware components, excluding the audio transducers of the ear probe and the battery are placed on the PCBs. All non-electronic mechanical parts of the prototypes were manufactured with stereolithography (SLA) 3D-printing.

Enclosure

Figure 3.6(a) shows a 3D render of the computer-aided design (CAD) model of the enclosure. The enclosure consist of two half-shells, which house all hardware components shown in Figure 3.6(b). The upper half-shell hooks into the lower half-shell at the bottom end. This point acts as a pivot, which locks both half-shells together. A single screw on the ear tip end fixes both half-shells in place. All components inside the enclosure are held in place without additional fasteners.

The resulting device is $30\,\mathrm{mm}$ wide and, without ear tip, $89\,\mathrm{mm}$ long. The body of the device has a height of $25\,\mathrm{mm}$ at the lower end, where the battery is located. The shape tapers towards the probe tip, to provide easier access into the patients ear. The device is intended to be held in the hand or between fingers and thumb during operation. A single thumb switch is used as user input, which can be manipulated by the examiner with the same thumb or fingers that are holding the device.

OAE Ear Probe

The OAE ear probe is integrated into the device enclosure. The performance of an OAE hearing screening device depends heavily on the ear probe. Since ear probe development was not a focus in this work, an existing ear probe was integrated into this standalone device. The ear probe head is based on a PATH medical GmbH [130] EP-DP DPOAE ear probe. This also allows to use the commercially available consumables, e.g. the soft ear tips.

Research into probe design is still ongoing in the Sound4All project. Future revisions of this device can then easily be adapted to new probe heads. A design goal for this new ear probe is to place the transducers, i.e. microphone and speakers, as surface-mounted device (SMD) components on the main PCB. This could potentially allow a more automated manufacturing process without manual soldering and fewer manual assembly steps.

3.4.2 Electronics

The overall design goal for the electronics was to use COTS components to implement the functionality as shown in Figure 3.1. In most cases, components were selected which are offered by manufactures for consumer products. The main exceptions are the audio transducers in the ear probe which are designed for hearing-aid applications. The electronics are arranged on two stacked PCBs, as shown in Figure 3.7. The front PCB provides two functions: The display and NFC. The latter includes the antenna, which requires about half the area of the front PCB. All remaining functionality is located on the main PCB.

Microcontroller

The selection of the processing platform was based on the experimental results of Section 3.3.2. A Silicon Labs EFM32WG330 MCU with an ARM Cortex-M4F core with floating point unit (FPU) was chosen. Along with all common peripherals, this IC offers $256\,\mathrm{KiB}$ of flash and $32\,\mathrm{KiB}$ of RAM. While the previous analysis shows, that much less computing capability is necessary, the MCU was deliberately overdimensioned, to accommodate future additions and experiments, for which this platform is primarily designed. The MCU is directly clocked from an $48\,\mathrm{MHz}$ main crystal oscillator, which is more power efficient than designs based on phase lock loops (PLLs) at this speed. While not strictly necessary for any other peripheral in this application, the crystal oscillator is required for USB communication. A secondary crystal oscillator with $32.768\,\mathrm{kHz}$ serves as long term time base for the real-time clock (RTC). This time base is intended for event logging and attributing OAE measurements with time stamps.

Peripheral connections inside the device are divided into those that need timing critical communication and non-timing critical communication. As the device has very little RAM available, the raw sample data from the audio interface would overflow the RAM in a few hundred milliseconds in most configurations. For that reason, all processing involving audio sample data is timing critical. Additionally, a single missing or delayed sample can introduce artifacts into the measurement. As a result, the audio codec IC is connected with a dedicated synchronous I²S bus. Similarly, the mass storage, implemented by a micro Secure Digital (SD) card, is connected with a dedicated Serial Peripheral Interface (SPI) connection. This allows to save data to the mass storage during an ongoing measurement.

All other peripherals are deemed non-timing critical and are connected via a shared Inter-Integrated Circuit (I²C) bus, e.g. audio codec IC configuration, display and NFC. Access to those peripherals is either done when no measurement is active or in case of the display in an best effort strategy with lower priority. Other connections include the debug connector, which is accessible from the outside of the enclosure, for step-by-step debugging in-situ, if necessary. A USB device is implemented, which can be used to remote control the standalone device and download the audio sample data in real time.

Audio

Due to the proliferation of smartphones, high performance audio codec ICs became available at low cost and small form factors. The used Dialog Semiconductor DA7217 provides the stereo ADC and DAC functionality, including the amplifiers, inside a $2\,\mathrm{mm}$ by $4.5\,\mathrm{mm}$ footprint. The sample data is transmitted with I²S, while configuration is controlled via I²C.

The audio codec IC can drive the two balanced armature speakers (Knowles HC-23772) in the ear probe directly. The biased audio signal from the ear probe microphone (Knowles EM-23346-C36) is filtered by a resistor-capacitor (RC) high-pass.

Human machine interface (HMI)

The HMI is kept minimal due to the limited device size, but also to follow the intention of a low-cost easy to use device. User input is implemented by a thumb switch, that can be operated by the same thumb or fingers that hold the device, allowing for a one hand operation. The other hand of the examiner remains available, for example to pull the patients ear back during probe insertion into the ear canal.

Output to the user is provided by a small graphical organic LED (OLED) display with $128\,\mathrm{Pixel}$ by $64\,\mathrm{Pixel}$ on a $22\,\mathrm{mm}$ by $11\,\mathrm{mm}$ area. The display is connected with the peripheral I²C bus.

Communication

The standalone device provides two means of communication with external devices: USB and NFC.

USB is mostly used for non-standalone experiments, where raw data needs to be transferred to another device. It is further used for calibration and to test the audio interface of the ear probe. If required, it could also provide access to the SD card, by registering as a mass storage device. However, the primary intended purpose during normal operation is to use the connector as a charging port, which allows the usage of common phone chargers.

Communication with a smartphone is carried out over NFC, which is enabled by a NXP NT3H2211 IC. The corresponding NFC antenna is implemented by copper traces directly on the front PCB. To start a communication, the standalone device needs to be held behind a smartphone which supports NFC. If the corresponding app on the smartphone is configured correctly, it is automatically opened and put in foreground once the standalone device is detected. By using predefined NFC Data Exchange Format (NDEF) messages, the app can then read from and write to the electrically erasable programmable read-only memory (EEPROM) in the NFC IC. For the intended use case with the standalone device, the communication can be completed in less than a second. The transferred data is used to set and read patient data, read corresponding screening result information and configure measurement parameters. Finally, the interface can also be used to set the RTC in the standalone device.

Storage

Mass storage is implemented with an microSD card, which is connected with a dedicated SPI bus. With common sizes of $8\,\mathrm{GiB}$ and more, SD cards offer enough storage data for multiple weeks of measurements. Besides patient data, the mass storage can also be used to collect other data, e.g. raw samples from the audio interface. During the experiments described in Section 3.7, the data from the additional sensors is also stored on the SD card. Due to the abundant memory size, data is saved uncompressed and American Standard Code for Information Interchange (ASCII) encoded, which allows for easy processing after the measurements are completed.

Power

All electronic components are selected to operate at $3\,\mathrm{V}$ or $1.8\,\mathrm{V}$. Each voltage rail is provided by a Microchip MCP1700 low-dropout (LDO) linear regulator. These voltage levels allow the device to be powered from a single rechargeable lithium-ion (Li-ion) battery cell. The battery cell is protected against overcharge, over-discharge, charge overcurrent and discharge overcurrent by an Texas Instruments BQ29707 IC. The battery is charged from the USB connector with a Texas Instruments BQ21040 charging IC.

The electronics are always connected to the battery, i.e. there is no power on switch. This allows the MCU to wake up on any interrupt event, e.g. a button press or on NFC communication. When no measurement is active, the device can be powered down either manually or automatically after a timeout. Most components have a quiescent sleep current of a few $\mu\mathrm{A}$. For components that do not support power down, i.e. the display and SD card, Texas Instruments TPS22929D power switches are used. Additionally, any pull-up resistors can be switched off, e.g. of the I^2C bus.

3.5 Software

The software running on the standalone device is, similar to the hardware, designed to be used in a research context. This implies, that the focus is not put on computational efficiency or resource usage. Instead, the main goal is a software architecture that is easy to understand and maintain. This strategy allows the standalone device to be adapted for use in other experiments.

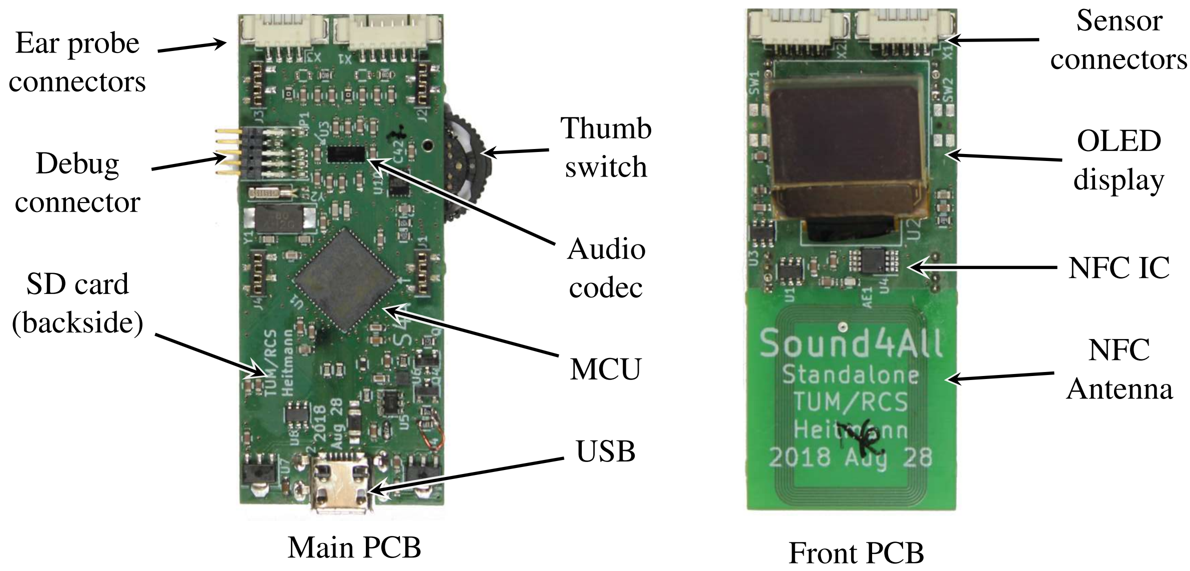


Figure 3.7: Annotated pictures of the main PCB and front PCB of the standalone OAE hearing screening device.

3.5.1 Real-time Tasks and Interrupts

The standalone device firmware uses the real-time operating system (RTOS) FreeRTOS [47]. This allows to divide the computing into independent tasks. By using a priority-based scheduler, the timing critical tasks can be separated from non-timing critical tasks. However, due to the limited available RAM in the MCU, instantiating tasks remains costly since each tasks needs its own stack and task control block (TCB). Additional to RTOS tasks, parts of the software are run in interrupt context. Notably, these deal with the audio buffers and associated DMAs management, before handing the sampling to a normal task execution context.

All tasks are instantiated at startup. The following tasks are used in the standalone device software:

Global Controller Task This task represents and controls the global state of the standalone device. Depending on external input, e.g. user input, battery levels, etc., the current device state changes. For example, when the user starts a DPOAE measurement, the device switches into the IEC state and after successful completion into the DPOAE measurement state. The high-level subroutines of these states are executed in the context of this tasks, which allows the reuse of the resources, i.e. task stack and TCB, since only one these states can be active at any time.

SD Card Task This task manages the mass storage provided by the SD card. After initialization of the peripherals and the SD card, it listens on a dedicated queue. The items in the queue are preformatted data, which is then written by this tasks to the appropriate file in the FAT32 file system.

Display Task Similar to the SD card task, the display task listens to a dedicated queue. The queue contains instructions on what to draw on the display, e.g. a screen with an ongoing TEOAE measurement. However, other tasks can also manipulate the display buffer directly and just put a display update command in the queue. This triggers the display task to write the current display buffer content to the display hardware.

Codec Memory Management Task The data coming from and going to the audio codec is completely handled in interrupt context. However, allocating and freeing memory can not be done from interrupt context, since the execution time can be noticeably non-deterministic.

NFC Task The NFC communication is asynchronous and only takes place when the smartphone is held close to the standalone device. When the communication is initiated, the smartphone reads from the integrated EEPROM of the NFC IC and writes data back to it using predefined NDEF messages. The NFC task keeps the NFC EEPROM contents up-to-date at all times and downloads new messages from it once they are available. Patient data is provided using shared memory. If an RTC update message is read, the task updates the RTC peripheral directly.

Sensor Task This tasks collects the data generated by the additional sensor hardware used in Sections 3.6 and writes the resulting data to the SD card tasks queue.

The architecture of the tasks and the associated inter-process communication (IPC) is designed for easy use and extensibility for future uses and experiments.

3.5.2 Global System States

The "global controller task" handles the global systems states of the standalone device, which are shown in Figure 3.8. These states serve to manage the limited resources of the device. In each state, the RAM and computing resources are reallocated to fit the demand of the current state. For example, during an ongoing DPOAE measurement, the frequency components are periodically extracted from the averaging buffer using an fast Fourier transform (FFT) algorithm. This requires at least buffers in RAM for the raw sample data, averaging data and frequency component data. However, no frequency extraction is necessary for the TEOAE, but windows of the sampled data have to be averaged in time domain.

After either OAE procedure is started by user input, the system switches into the IEC state. The software continuously checks, if the acoustical conditions described in Section 2.4.5 are met. This allows the user to start the measurement before inserting the probe tip into the ear. Once the IEC has completed successfully, the system switches into the selected measurement state, i.e. DPOAE or TEOAE. Once in a measurement state, the actual OAE measurement begins. If changes in the probe fit are detected, the state changes back into the IEC state for a recalibration. When the measurement is completed, the results are displayed as the state changes back to Idle.

For simplicity, transitions for handling manual abortion of the procedures, failed self checks and timeouts, as well as states and transitions for the power management are not shown in

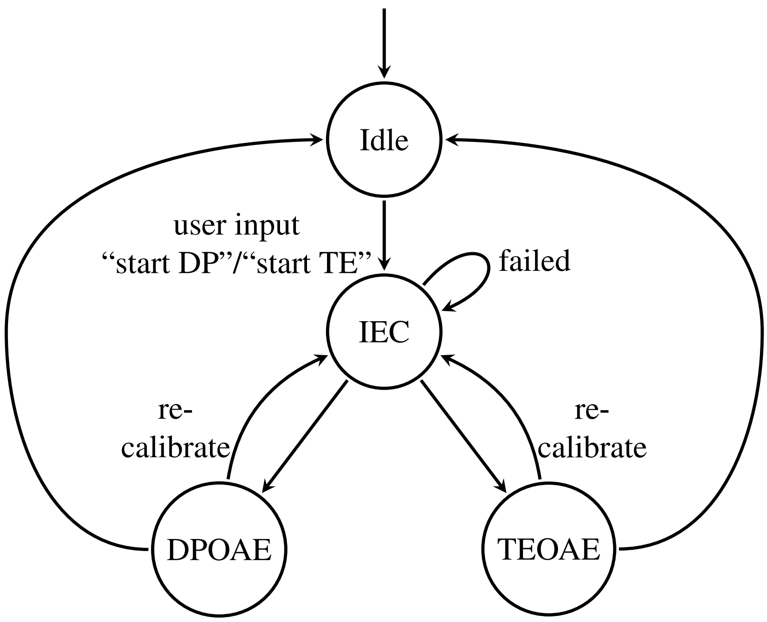


Figure 3.8: Simplified diagram of the global system states of the standalone device.

Figure 3.8. If the charge levels of the battery is low, the system does not switch into any active measurement states.

3.5.3 OAE Measurement

The actual measurement of OAEs takes place when the system is in the corresponding state. Each measurement is a subroutine of the “global controller task”, which interacts with the other software components to set the stimulus and acquire the microphone samples. The fully automated measurement procedure for TEOAE and DPOAE is similar to the procedures described by Whitehead et al. [174].

3.6 Extra Sensors

The standalone device serves as a platform not only to investigate a low-cost OAE solution. Another goal is to make the device easy to use by laypersons. The major challenge, aside from environmental and physiological noise, when measuring OAEs is to fit the ear probe tip correctly into the ear canal. In this section, additional sensing hardware is added to the device to acquire data of the insertion process into the ear, as well as during the actual OAE measurement. The goal is to use this data to detect patterns, which not only indicate a problematic probe placement, but might also allow to give interactive feedback to the examiner who is using the device in how to correct the placement if a problem exists.

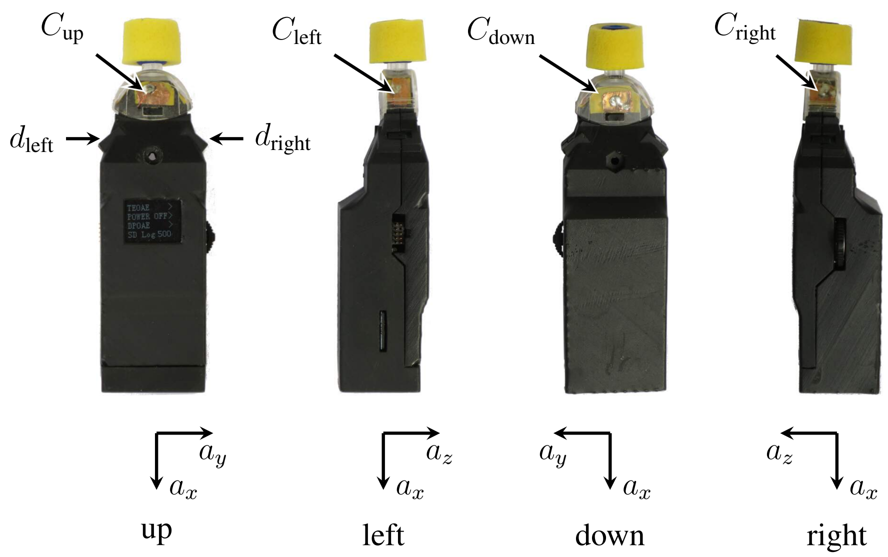


Figure 3.9: Photograph of the standalone OAE screening device with labeled additional sensors.

3.6.1 Additional Hardware

The existing standalone device hardware was supplemented with a range of low-cost sensors. Figure 3.9 shows where the sensors are located on the device and how they are oriented.

Capacitive Sensing

Close proximity to the ear can be detected with capacitive sensing, where the capacitance of a pair of electrodes is measured. The measured capacitance across the electrodes changes, when different materials are placed in their electric field. In this application, the different materials are air and the human body of the patient.

Four copper electrodes are arranged around the ear probe of the standalone device as shown in Figure 3.9. During an OAE measurement, the electrodes are covered by the plastic ear probe tip. Each electrode is approximately $1\,\mathrm{cm}^2$ in area. The electrodes capacitance is measured against the ground plane of the standalone device, which forms the second electrode for each measurement. Figure 3.10 shows the comparator circuitry, which is part of the used MCU. One of the capacities, formed by the electrodes, is selected using a multiplexer. The selected capacity and the fixed resistor R_1 in the feedback path form an RC network, which, together with the comparator, whose high and low thresholds are fixed, results in a free-running oscillator. The oscillation frequency, or inversely charge-discharge cycle time, will change, dependent on the capacitance of the selected electrode. If the capacitance increases, e.g. due to a human body being close to the electrode, it takes longer to charge the capacitance through the feedback resistor, thus lowering the frequency. The frequency is measured by feeding the oscillator signal into a counter, which increments with each rising edge. A second counter, configured as a timer with a fixed period T_{count}, is used as a time-base to periodically store the value of the first counter and reset its count value. With this procedure, an integer value with fixed equidistant

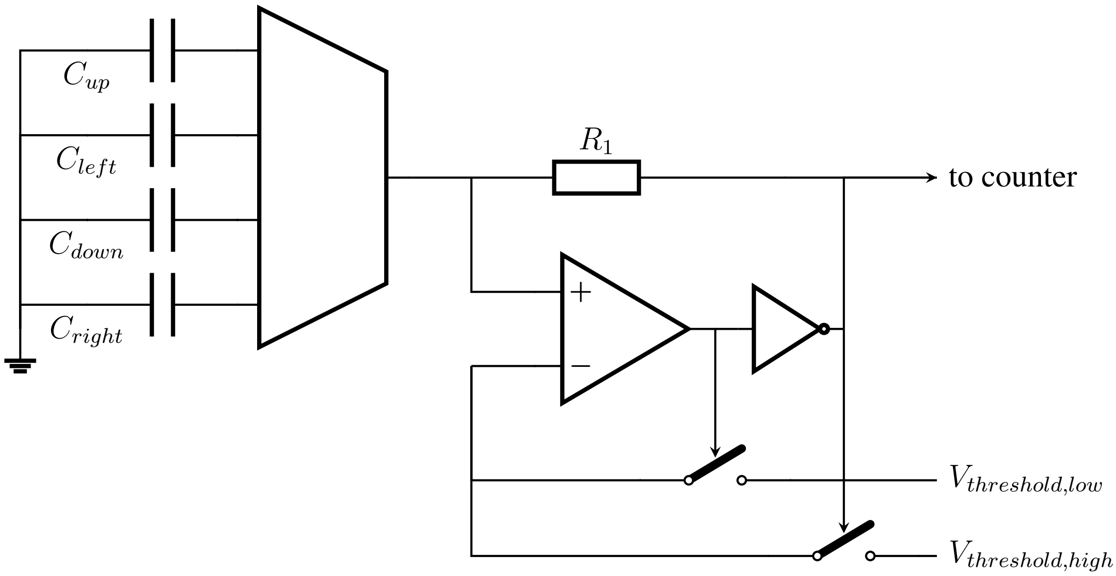


Figure 3.10: Schematic of the oscillator used to measure the capacitance of the four ground referenced copper electrodes at the ear probe tip.

sampling synchronous to the MCU system clock is obtained, which corresponds to number of charge cycles of the selected electrode per time interval T_{count}.

The acquired value is inversely proportional to the capacitance of the electrode. However, the absolute capacitance value depends on environmental influences like temperature and humidity. The data obtained from this source is thus only used in a relative manner, e.g. by calculating the ratio of the values before and after inserting the ear probe into the ear.

Distance Sensing

Due to the small electrodes, the capacitive sensing has only a sensitive range of up to approximately $10\,\mathrm{mm}$. Further, the resulting values reflect the capacitance of each electrode, but not necessarily the distance to an object, which makes them more useful to detect small motions and relative changes. For this reason, a second sensor type is used to measure distance: A pair of ST VL6180X distance sensors, which are based on the time of flight (ToF) of infrared light. These sensors are placed on small external PCBs, which are mounted just behind the ear probe on the main standalone device body, facing outwards at an angle of $40°$. The range is up to $100\,\mathrm{mm}$ with a $1\,\mathrm{mm}$ resolution. I^2C is used to connect the sensors, which must be polled by software. The maximum sensible sampling rate is limited to about $1\,\mathrm{Hz}$. Additionally, the software combined with the shared hardware connection results in a considerable jitter.

Inertial measurement units

An inertial measurement unit (IMU) is used to obtain acceleration and turn rate data. This data can be used to calculate the attitude of the standalone device during the measurement. Since usually no acceleration forces act on the standalone device, except the gravitational force of the earth, just acceleration data can be directly used to measure two of the three orthogonal angles in 3D space.

In the standalone device, an ST LSM6DS3H based on micro-electro-mechanical systems (MEMS) technology is used, providing three axis of acceleration and angular rate each. It is connected via I²C with built-in first in, first out (FIFO) buffer and has an interrupt line connected to the MCU. However, timing is again derived from on internal asynchronous RC oscillator-based clock.

3.6.2 Sensor Data Collection Software

The sensor data collection is mostly independent of the remaining software on the standalone device. The data from the distance sensor and the IMU is collected by a dedicated task, while the capacitive sensing utilizes the DMA and interrupt system. Both sources continuously write the data measured by the extra sensors to the SD card, even in the idle state. This allows the collection of the extra sensor data during the insertions of the ear probe into the ear canal, before the IEC and the actual OAE measurement procedure begins. The data is stored in plain text ASCII. Each value from each sensor source is attributed with a time stamp, which is based on the system clock.

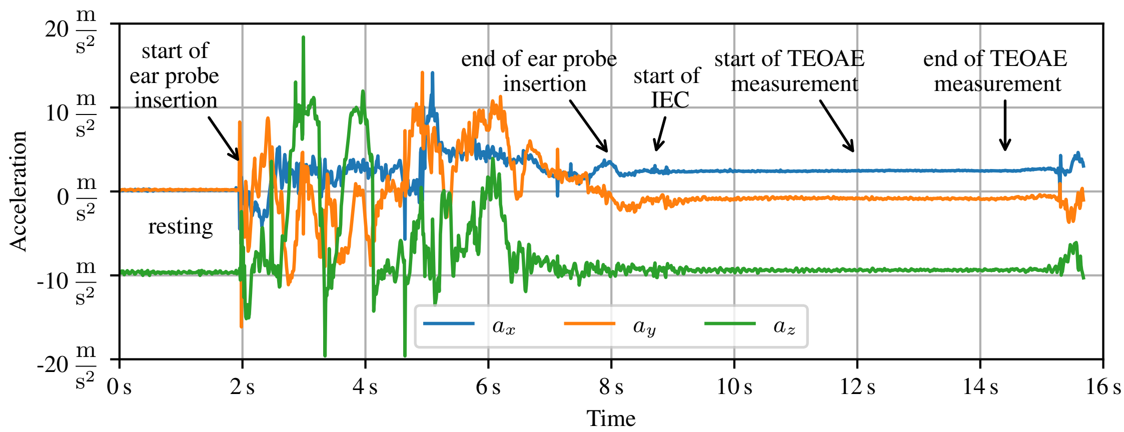
3.6.3 Sensor Data Preview

Figure 3.11 shows an example recording of the extra sensors during a TEOAE measurement. In this measurement, the stand alone device's ear probe was inserted into the right ear of an adult with the display facing upwards. As shown in the annotations of Figure 3.11(a), the process of measuring OAEs can be divided in multiple phases: In the first $2\,\mathrm{s}$, the device is resting on a solid surface, which results in a constant reading of all sensors. The acceleration sensor responds to the gravitational force, which results in approximately $9.81\,\mathrm{m^2/s}$ on the vertical sensor axis a_z, while the remaining axes a_x and a_y read almost zero. This indicates, that the device was placed with the display facing up. At the same time, distance sensors, which have a field of view (FoV) of a few degrees, respond to objects close by. Since there is only air in front of the standalone device, the capacitance is at its lowest for each electrode. This results in the maximum "charge cycles" readout per electrode.

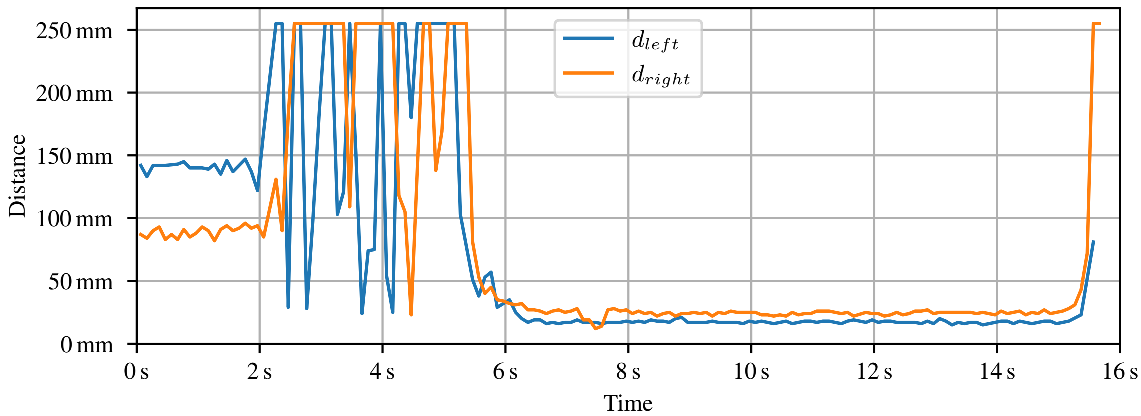
The next phase is the ear probe insertion, which takes $6\,\mathrm{s}$. As the probe tip is placed in the ear canal, the sensor readout changes erratically. This can be mostly attributed to handling the ear probe tip, i.e. replacing or seating the soft tip. At $5\,\mathrm{s}$, the actual insertion starts, which can be identified by the uniform decrease of the distance sensor readings. The examiner makes a final adjustment of the ear probe at $7\,\mathrm{s}$, when the distance sensors are almost at their final resting values, which is the steady state during the actual OAE measurement. At this close proximity, the capacitive sensors become more sensitive and can reveal marginal adjustments.

The actual measurement procedure starts with the press of the thumb on the switch button at approximately $8.5\,\mathrm{s}$. The automated measurement protocol starts the IEC and upon successful completion automatically proceeds to the actual OAE measurement, which completes $6\,\mathrm{s}$ later. During the whole measurement phase, the probe must be held steady. This results in almost constant readings from all sensors.

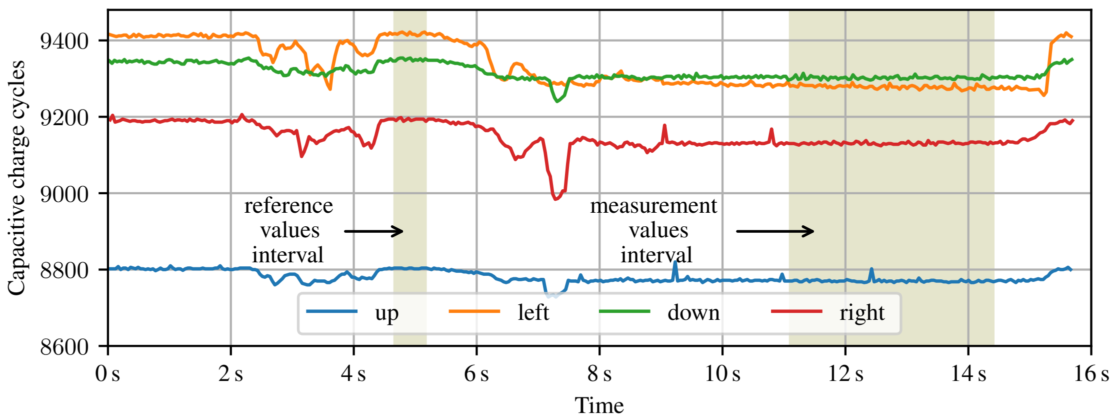
Once the measurement is complete, the probe is removed from the ear at $15\,\mathrm{s}$.



(a) Acceleration sensor reading including annotations of the measurement phases.



(b) Distance sensors readings. The maximum distance value the sensor can output is $255\,\mathrm{mm}$.



(c) Number of charge cycles per measurement interval. The capacitance rises, when the ear gets close, thus lowering the number of cycles per interval.

Figure 3.11: The standalone device's ear probe is inserted in a right ear with the display facing up.

Table 3.1: Standalone device attitudes during measurement and the expected gravitational acceleration with $\mathrm{g} \approx 9.81\,\mathrm{m}^2/\mathrm{s}$.

Attitude	Expected acceleration			
	a_x	a_y	a_z	Θ
up	0	0	$-\mathrm{g}$	180°
left	0	g	0	90°
down	0	0	g	0°
right	0	$-\mathrm{g}$	0	270°

3.7 Ear Side Detection

During hearing screening, both ears must be tested and the result documented. However, especially to laypersons, documenting the correct side of the ear might be confusing or forgotten. Further, the user interface must have an additional input to select the current ear, if the data is stored in the device or a connected smartphone. This can be error prone, for example, if an ear side is selected, but the opposite ear is measured first. Correcting faulty inputs afterwards, requires even more involved user interfaces. The error rate and complexity could be lowered, if the measurement system was able to detect the current ear side by itself.

In this section, the data of the additional sensors from Section 3.6 is used. Most of the data was collected as part of a research internship by Eisenlauer [41], where a small study was conducted with 10 adults. Four TEOAEs tests were performed in each of the 20 ears, resulting in 80 measurements. Between each measurement in the same ear, the standalone device was rotated 90° degrees before being reinserted in the ear canal. The four possible attitudes of the standalone device are shown in Figure 3.9 and are from here on referred to as “up”, “left”, “down” and “right”, each referring to which side of the standalone device is facing upwards. During all measurements, the data from the extra sensors was collected and stored in the internal storage for later offline analysis.

3.7.1 Attitude of the Ear Probe

As can be seen in Figure 3.11, the sensor readings are almost constant during the actual OAE measurement phase. Since there is no additional motion present, the readout of the acceleration sensor can be used to estimate the attitude of the standalone device relative to the gravitational force. Using the three components of the acceleration vector as it is read from the sensor allows the deduction of two of the three attitude angles. However, in the context of this experiment, we are only interested in estimating the “cardinal” attitudes as they were used during the measurements, which is the rotation along the center line, i.e. the axis from the probe tip to the USB connector. As can be seen in Figure 3.9, this angle depends only the a_y and a_z component of the acceleration data from the sensor. The a_x component is close to zero in all measurements.

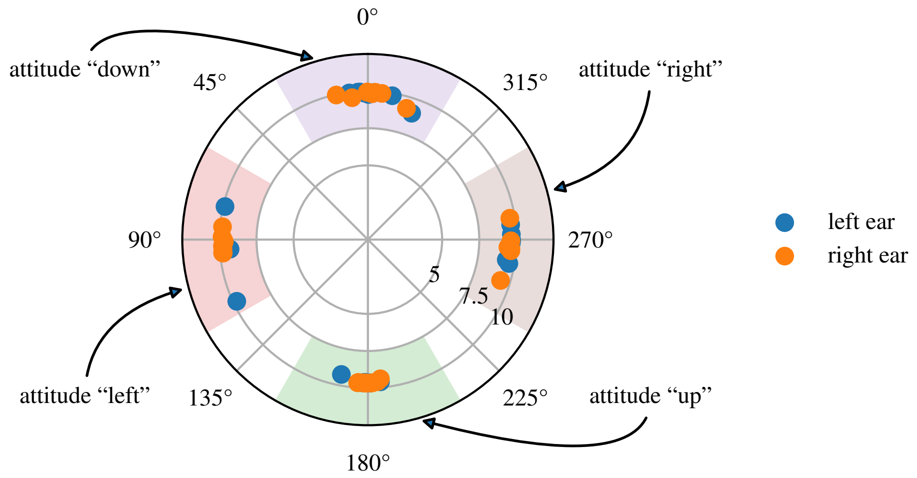


Figure 3.12: Magnitude in $\mathrm{m/s^2}$ and angle of the acceleration relative to the up direction during the measurements. Highlighted are the areas used for the four attitude categories.

The resulting angle Θ and the magnitude of the acceleration vector is

$$\Theta = \arctan \frac{a_y}{a_z} \qquad (3.1)$$
$$|a| = \sqrt{{a_y}^2 + {a_z}^2}.$$

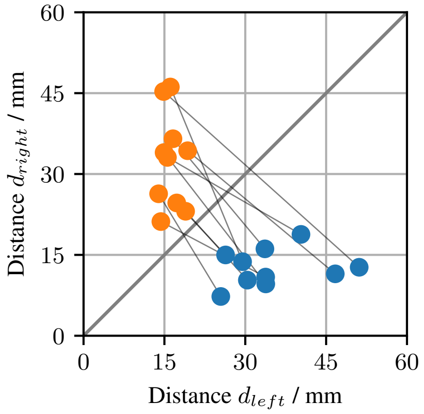
Table 3.1 shows the expected acceleration vector components for each attitude and the resulting angle Θ.

In each measurement, the recorded acceleration data a is averaged in the time interval from the start of the TEOAE procedure until its end. Figure 3.12 shows the result of applying Equation 3.1. All resulting angles fall within a $30°$ margin around the four “cardinal” attitudes. Additionally, all magnitudes are close to the gravitational acceleration of $9.81\,\mathrm{m^2/s}$. The most prominent source of error in the acceleration magnitude can be attributed to a tilt along the y-axis or z-axis during measurement. The figure also shows the ear, i.e. left or right, in which each measurement was taken. However, no correlation between the acceleration data and the ear side was found.

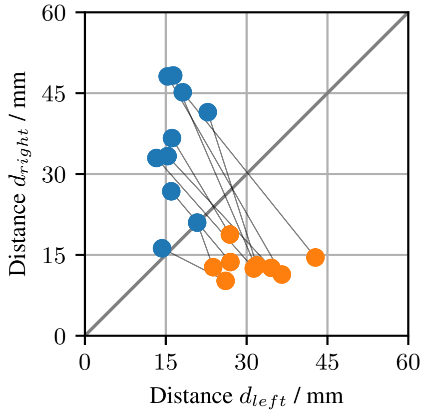
Due to the calm and steady nature of OAE measurements, the acceleration data is ideally suited for attitude estimation. Additional data sources or sensor data fusion, e.g. by also using the turn-rate data of the gyroscope or a magnetometer, would not significantly improve the attitude estimation. The high quality of the data also lends itself to be used with arbitrary angles, and not only the four discrete attitudes of this experiment. However, due to the limited numbers of samples in this study, the discrete approach was chosen.

3.7.2 Distance

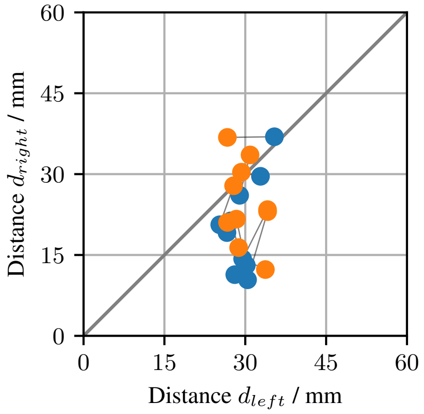
The distance sensors deliver absolute distance values in a range of $0\,\mathrm{mm}$ to $250\,\mathrm{mm}$. Figure 3.13 plots both sensors against each other, which results in 20 measurements per attitude. The used



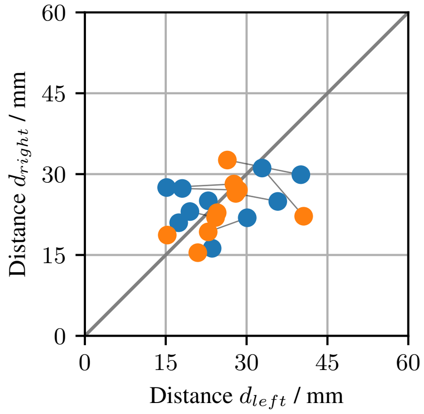
(a) Attitude “up”.



(b) Attitude “down”.



(c) Attitude “left”.



(d) Attitude “right”.

Figure 3.13: Distance sensor readings for each attitude.

distance value representing each measurement is the mean value of all distance sensor readings between the start and end of the TEOAE procedure.

Figure 3.13(a) and (b) show a significant separation of both sensor values for the left and right ear in either the “up” or “down” attitude. In these cases, the distance sensors are on the horizontal plane, i.e. one sensor is facing backwards towards the auricle and the other forwards. The auricle is detected by the d_{right} sensor in the “up” attitude and d_{left} sensor in the “down” attitude respectively. If the auricle is in front of either sensor, the average reading is $14.7\,\mathrm{mm}$ with an standard deviation (SD) of $3.2\,\mathrm{mm}$. The opposite sensor will range against the head just in front of the tragus, where the average reading is $33.5\,\mathrm{mm}$ with an SD of $8.6\,\mathrm{mm}$. Classification into left and right ear can simply be achieved by comparing both distance values to each other. A full recording of an “up” measurement can be seen in Figure 3.11(b).

Figure 3.13(c) and (d) show the measurement results if the distance sensors are in a vertical plane. The lower sensor, d_{right} in the “left” attitude and d_{left} in the “right” attitude, ranges approximately against the ear lobe at an average distance of $24.1\,\mathrm{mm}$ with an SD of $7.9\,\mathrm{mm}$.

While the respective opposite sensor usually detects the helix of the auricle at an average of $26.9\,\mathrm{mm}$ and SD $4.89\,\mathrm{mm}$. In this configuration no significant correlation between both sensor readings was found.

The results show promising possibilities for ear side detection, if the distance sensors are placed such that one sensor detects the auricle. Even with the limited amount of data of this trial, the results show a very feasible approach in using the ToF distance sensors for ear side classification.

3.7.3 Capacitive

The capacitive sensing with the copper electrodes at the ear probe tip is well suited for detection small changes if the ear is at close proximity. However, the data from the capacitive sensing cannot directly be used for an analysis. The absolute capacitance and thus the value of the reading will change under environmental influences. Most notably are varying temperature and water content of the material, i.e. the air and the human body, in the electric field of the capacitor.

Preprocessing

To compensate this variability, only relative changes of the capacitance to an reference value will be used. The reference value is the capacitance of air, i.e. when no objects are in front of the ear probe. To obtain appropriate values, the distance sensor data is evaluated to identify a suitable time interval where no objects are detected by the distance sensors just before insertion of the ear probe.

The sum of the signal of both distance sensors, d_{right} and d_{left} is convolved with a box kernel $g[n]$:

$$g[n] = \begin{cases} 1, & \text{if } 0 \leq n < \Delta T_{box} \times f_{s,distance} \\ 0, & \text{otherwise} \end{cases}$$

$$d_{stable}[n] = ((d_{right} + d_{left}) * g) \tag{3.2}$$

$$= \sum_{m=0}^{N_{dist}} (d_{right}[m] + d_{left}[m])g[n-m] \tag{3.3}$$

The length of the box kernel is set to $\Delta T_{box} = 0.5\,\mathrm{s}$ and the sampling frequency of the distance sensors is $f_{s,distance} = 10\,\mathrm{Hz}$. The reference time interval is centered around the time $T_{cap,stable}$, where the maximum value of the resulting sequence occurs:

$$t_{cap,stable} = \frac{\arg\max_n d_{stable}[n]}{f_{s,distance}} \tag{3.4}$$

Figure 3.11(c) shows an example of when the reference interval is placed, which has a width of ΔT_{box}. The mean of the capacitance charge cycle values in this time interval is used as the reference value $N_{\text{cap,ref}}$. Equivalent to the acceleration data and distance data analysis, the capacitance charge cycle values during the actual TEOAE measurement are averaged and used as

Table 3.2: Correct ear side classifications using the capacitive sensor data for each standalone device attitude with $n = 20$ measurements per attitude.

Attitude	Correct classifications
up	$80\,\%$
left	$75\,\%$
down	$75\,\%$
right	$70\,\%$

the measurement values $N_{\text{cap,meas}}$. Since the capacitance charge cycle values are inversely proportional to the actual capacitance of the measured electrode, the relative change of capacitance can now be obtained as

$$\text{relative change } C = \frac{N_{\text{cap,ref}}}{N_{\text{cap,meas}}} - 1. \tag{3.5}$$

The reference capacitance value $N_{\text{cap,ref}}$ and measurement capacitance value $N_{\text{cap,meas}}$ and the resulting relative capacitance change C_{rel} are obtained for each of the four sensors and each of the OAE measurements in this experiment.

Results

Figure 3.14 shows the results for each standalone device attitude. For each attitude, the capacitance change of the opposing electrodes are shown, i.e. C_{up} vs. C_{down} and C_{left} vs. C_{right}. In the "up" and "down" attitudes, shown in Figure 3.14(a) and (b), the electrodes C_{left} and C_{right} are in the horizontal plane and thus one of them is always facing the auricle, while the other faces the tragus. A distinct separation of values, dependent on the ear side can be observed in the results. In the vertical plane (C_{up} and C_{down}), the sensor facing the ear lobe shows a distinct increase in capacitance. However, since the vertical plane is in line with the acceleration and the ear side is on an orthogonal plane, no additional information regarding the ear side is obtained.

Similar results were observed for the "left" and "right" attitudes, as shown in Figure 3.14(c) and (d). In these attitudes the C_{up} and C_{down} are in the horizontal plane. The separation of the measured values is still present, but not as clear compared to the previous results. At the same time, the detection of the ear lobe remains similar.

From these results it can be concluded, that the relative capacitance change for each opposing pair of electrodes is dependent on the ear side, if the electrodes are in the horizontal plane. However, the dispersion of the measured values is high enough, such that a completely correct classification of the ear side is not directly possible using the collected data. Table 3.2 shows the result of using a simple classifier, which selects the highest measured value in the horizontal plane to detect the auricle and thus the ear side. Slightly better results were obtained when C_{left} and C_{right} were in the horizontal plane (attitudes "up" and "down").

It should be noted, that the electrodes of C_{left} and C_{right} differ significantly from the electrodes of C_{up} and C_{down}. As can be seen in Figure 3.9, the ear probe is not rotation-symmetric.

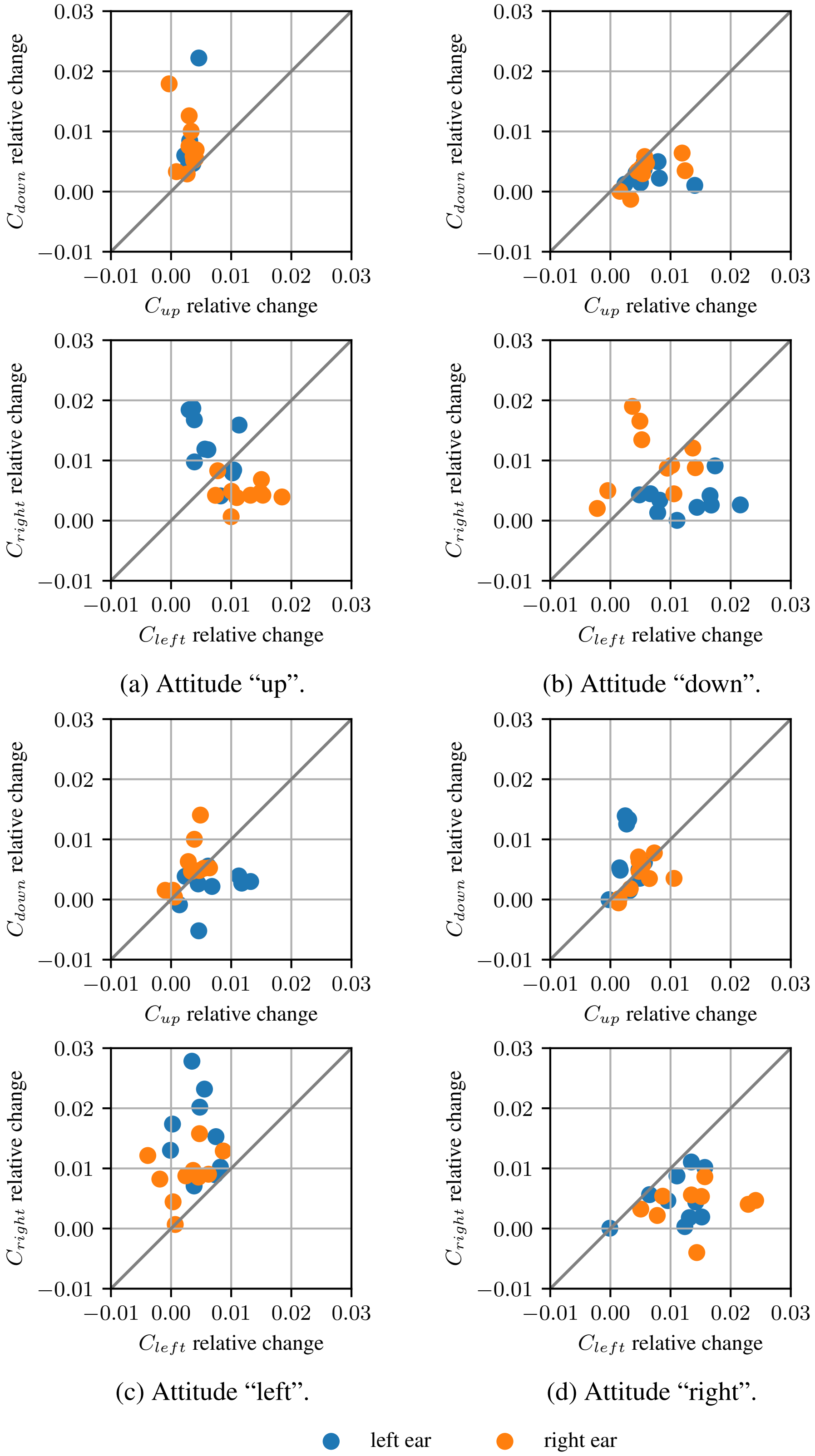


Figure 3.14: Relative changes of the capacitance values during ear probe insertion.

Table 3.3: Mean and standard deviation of the relative change of each capacitive sensor (in %), depending on which part of the ear the capacitive sensor is facing.

Capacitive sensor	Horizontal		Vertical	
	Auricle	Tragus	Lobe	Helix
C_{up}	0.58 ± 0.35	0.31 ± 0.30	0.62 ± 0.32	0.31 ± 0.19
C_{down}	0.60 ± 0.45	0.31 ± 0.21	0.76 ± 0.49	0.30 ± 0.11
C_{left}	1.24 ± 0.46	0.40 ± 0.22	1.36 ± 0.73	0.46 ± 0.37
C_{right}	1.11 ± 0.52	0.68 ± 0.44	1.21 ± 0.64	0.35 ± 0.34

Most notably, the electrodes of C_{left} and C_{right} are positioned further outwards and tend to be closer to any nearby skin, which leads to higher amplitudes once the probe is inserted.

A slightly different summary of the measurement results can be seen in Table 3.3. For each capacitive sensor, the measured values are grouped by the part of the ear the sensor faces. Again, a distinct separation between the measured values of auricle and tragus as well as lobe and helix can be found. The separation is usually higher for C_{left} and C_{right}. However, given the measured dispersion of the results, the separation is still too small for a highly reliable ear side classification.

3.7.4 Discussion

In this section, the extra sensors from Section 3.6 were applied to classify, in which ear (left-/right) the probe was inserted during a TEOAE measurement. The attitude of the standalone device, in respect to the gravity, was obtained using acceleration data, which proved to be very reliably, due to the calm and steady nature of OAE measurements.

Two ToF distance sensors mounted close to the probe tip were able to reliably detect the ear side, if the device's attitude was such, that the distance sensors were in a horizontal plane. In this case, one distance sensor measures against the auricle, while the other measures just in front of the lobe. An average difference of approximately $18\,\text{mm}$ was measured. While the ear side detection by distance sensor was very reliable, the drawbacks are that these ToF sensors need an unobstructed line of sight to the target, which might add additional challenges in term of hygiene/cleaning or simply on subjects with long open hair. In addition, the sensors are more expensive and integrating them is more complex compared to the capacitive sensors.

While the four capacitive sensors showed on average meaningful separation between the electrodes facing the auricle and the opposing direction, reliable detection of the ear side was still not possible due to the high dispersion in the measurement values. With a simple classifier, which compares the the opposing capacitive change readings from the opposing electrodes, the classifier was only $75\,\%$ correct. The capacitive sensors show a dependency on where the electrodes are exactly placed. Thus investigating better placement, shape and size of the electrodes might also improve the error rate.

An automatic ear side detection system could improve the usability of any screening system, by lowering the human error during patient data input. Such a system could also be used to interactively augment the probe insertion, e.g. by suggesting the measured side and informing the examiner, if there is a high certainty, that the ear side was mixed up.

3.8 Chapter Summary

In this chapter, a simplified standalone OAE hearing screening device was presented. The design is based on a systematic analysis of hardware requirements in the context of computational offloading to a connected smartphone. The results of this analysis showed, however, that the most beneficial partition of computation is to either move all of the computation into the smartphone or all of the computation onto the screening device.

In this chapter, the latter architecture was explored, completing the device with a minimal human machine interface (HMI) to a full standalone device. The smartphone connection remains optional for patient data management and configuration using a NFC interface for communication. A novel approach was chosen, in which the complete system is integrated into a single body, including the ear probe. With the ear probe merged into the device, no connectors and external cables are necessary. Thus, this device architecture lowers the component count, but also the complexity of manufacturing such a device. Further, since the probe is permanently connected to the body, any device specific calibration or other data can be stored in the internal memory during manufacture and initial calibration.

This screening device design provides a platform for low-cost hearing screening experiments. Due to its extensible design, the standalone OAE device offers itself for experiment specific modifications. In a second phase, extra sensors were added to gain information on the probe insertion process. A small study was conducted, in which the data of the extra sensors was used to detect, in which ear the probe was inserted. The ToF distance sensors provided promising results, while the error rate on the capacitance-based approach was too high to be useful.

Future work

The standalone device uses the ear probe design of a commercially available DPOAE probe, since the focus of this work was the hardware and processing platform that connects to the probe. However, in a following step, the probe could be further integrated into the design. Currently, the internal connection between the PCBs and the transducers is implemented by individual coated wires, which still need to be hand soldered. Further integration could be achieved by an ear probe design, where the transducers are mounted as SMD components on the main PCBs, which need to extend further into the ear probe. The acoustic channels, which connect the transducers to the probe tip, could then be formed by prefabricated pieces that get glued or clamped to the PCBs. Such a design could be manufactured with fewer manual assembly steps and at the same time remove the error prone hand soldering process.

Furthermore, in the experiments described in Section 3.7, only the data of 20 ears was available. In a follow-up, a larger number of samples would be required. Additionally, since OAE-based hearing screening is often used with small children, a more diverse age range is needed. More data would allow a better statistical analysis or allow machine learning. With the data collected by the device, the correct ear side could be estimated if the head is upright. The current system could, with minor modification, also be used if the patient lies down on the back. Finally, an interactive feedback during probe placement, using the sensor data, could help with probe insertion and immediately show the detected ear side.

4
Smartphone-based OAE Hearing Screening

In this chapter, we present a novel objective hearing screening system based on smartphones. In contrast to the approach of the last chapter, where all functionality was moved outside a smartphone, here the smartphone takes over almost the full functionality. By utilizing the existing audio subsystem and a commercially available otoacoustic emission (OAE) ear probe, which is connected to the headphone jack, the required external hardware is kept to a minimum. Since smartphones are ubiquitous around the world, many people are familiar with their usage, which potentially makes measuring accessible, even for laypersons.

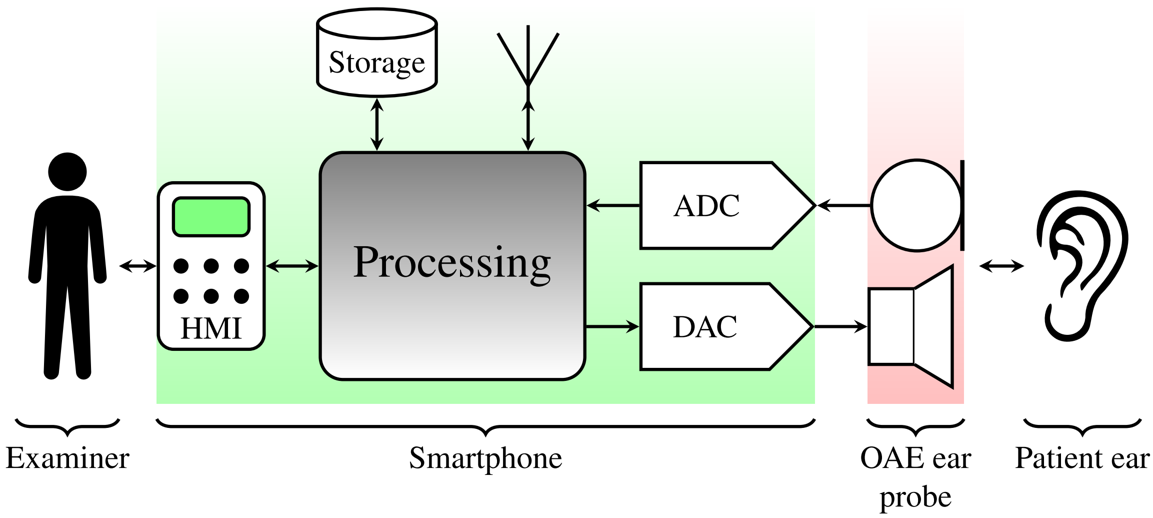


Figure 4.1: Schematic overview of an OAE screening device based on a smartphone. The headphone connector and the audio subsystem are used to interface the OAE ear probe. All required components are commonly present in any smartphone.

4.1 Introduction

With 430 million people suffering from moderate to high hearing loss, it is one of the most widespread disabilities in the world [182]. Even a moderate loss can impact communication, well-being, quality of life, and health. This problem is more severe in developing and under-developed countries. In a study among Indian school children [109] aged between 12-14 years, researchers screened 1,030 urban children and found that 6% of them suffered from some kind of hearing loss compared to nearly 33% in the rural group of 640 children. The difference might be attributed to the lower socio-economic status of the rural population often leading to malnutrition, poorer health education and inadequate medical facilities which all increase the risk of hearing problems. Also, according to a study carried out by the Society to Aid the Hearing Impaired, in many cities in India (such as Hyderabad and Kolkata) three out of four traffic patrol officers suffered from some form of hearing loss (sometimes even permanent ones). Similar numbers have been found in industrial environments where often safety gears are not used or norms are not strictly followed.

In all of these cases, the deterioration is *progressive* and timely detection and intervention can reduce or completely address the problem. However, in such scenarios, there is also a lack of suitable medical facilities and personnel, and cost is an added constraint. To address these, the goal of our research has been to develop a (i) low-cost *hearing screening* device, that (ii) can be operated by a layperson without any medical training. We envision such a device to be used in rural schools, where the class teacher might screen every child once a year, and refer to a doctor for more detailed examination if the test fails. Or they could be used by construction workers or traffic police and detect the onset of hearing issues in a timely manner.

In this chapter, we ask *whether a smartphone could be a suitable platform for such a hearing screening device*? Today, smartphones have very high penetration in both developing and under-developed countries and would address requirement (i). Not surprisingly, there are already multiple smartphone apps for hearing screening; see [21] for a review. However, all of these apps rely on what is referred to as *subjective* tests, where the smartphone plays a sequence of tones through a headphone into the subject's ear, who has to give feedback on hearing the tone. However, such tests are not suitable, for example, in a rural school for various reasons – children cannot give reliable feedback, each test takes too long, and there is often considerable ambient noise. Hence, we ask a more specific question in this chapter: Whether a smartphone could be a suitable platform for *objective* screening tests?

Technical challenges: Unlike subjective tests, objective ones do not require any interaction with the subject and are much faster. While more details are in the subsequent sections, here we are concerned with objective tests based on OAEs. Here, acoustic stimuli are emitted into the subject's ear canal and based on how these tones are distorted by the active processes in the cochlea (in the inner ear), a characteristic acoustic emission can be detected in the ear canal from which the hearing (dis)ability of the subject can be deduced. Although there are commercially-available medical devices based on this principle, they are expensive (in the range of five to ten thousand dollars and upwards) and can only be used by trained medical personnel. Our goal is to investigate whether a smartphone with a simple interface could instead provide reliable results. This is fraught with some technical challenges – unlike smartphone-based subjective tests, we now need the input (microphone) path of the smartphone to detect a signal that is well below normal ambient noise. Since the audio subsystems of smartphones are not designed for detecting such low signals, it is not clear whether a smartphone can at all be used, and what kind of signal processing techniques could be necessary for detecting such signals. Second, we aimed to use the standard Android application programming interface (API) in order to develop a general enough solution. Unfortunately, it offers little access to the smartphone's hardware, making our problem more difficult.

Contributions and outcomes: We evaluated seven off-the-shelf smartphones and found that four of them are suitable for OAE-based hearing screening. While all the smartphone could generate suitable stimulus signals, their return paths had very different characteristics. First, we had to check the sound pressure in the ear canal (at the microphone) and what digital values it resulted from the analog-to-digital converter (ADC) in the smartphone. This input-signal path behaved in a non-linear fashion in some smartphones (Motorola G4 Play and Fairphone FP 3), rendering them unsuitable. Second, the reflected signal from the cochlea has to be filtered from ambient noise. This can be done using standard methods (such as synchronous averaging) as long as the phone does not introduce additional distortions. Because OAEs themselves are also distortions, in the presence of additional distortions introduced by the smartphone, we will not be able to reliably detect them. One of our evaluated smartphones (Huawei Nova) failed this requirement. Among the evaluated phones, the Samsung Tab A 10.1, LG G5 SE, Sony Xperia Z3+ and Google Nexus 7 passed all requirements and turned out to be suitable.

Using suitable signal processing algorithms and by comparing with results from standard medical devices, we conclude that smartphone-based *objective* hearing screening is feasible. Our interface – with a simple "pass"/"refer" outcome – is suitable for use by a layperson with little to no training. Hence, we believe that this could result in a solution for mass-deployable hearing screening in developing countries, where a low-cost hearing screening solution, without involving trained medical personnel, is necessary.

To the best of our knowledge, this is the first work that investigates smartphone-based *objective* hearing screening. Combined with existing subjective screening apps that use different interaction modalities with a subject, *viz.,* explicit feedback, this work opens up more possibilities. Our proposed objective test can be administered very rapidly. If it fails, then a more detailed and carefully orchestrated subjective test, again using a smartphone, but with a different app and headset, can be administered. Subsequently, the subject might be referred to a medical practitioner if needed. But a first rapid objective test significantly enlarges the pool of subjects who can now be tested. As explained in this chapter, there are also opportunities for improving the signal processing techniques we use, to further reduce the screening time per subject and bringing the performance closer to that of specialized medical-grade screening devices.

In the next section, we introduce the relevant concepts of hearing screening and explain the used OAE measurement protocols. Section 4.3 discusses how we set up the different smartphones in order to evaluate them for objective hearing screening. In Section 4.4, the audio input and output paths of the smartphones are characterized. Finally, in Section 4.5, we conduct OAE measurements with the smartphones and compare the results with those obtained using a medical-grade equipment.

4.2 Basics of Hearing Screening

This section gives a brief introduction to hearing screening and the measurement of OAEs to a degree of detail, that is relevant for the work in this chapter. For a more detailed review, the reader is referred to Chapter 2.

In audiology, hearing tests can be categorized into *diagnostic* and *screening* tests. Diagnostic tests are used in a clinical setting to examine the auditory system of a patient in detail, to identify diseases and find appropriate treatments. Screening tests, however, are intended to quickly evaluate the state of the auditory system, to discern if a diagnostic test in a clinical setting is necessary. The result of such a test is either a "*pass*" if the hearing is normal, or a "*refer*" if a normal hearing could not be established. In the latter case, the patient is referred to a doctor for a detailed diagnostic test, since the cause of a "refer" could also be, for example, a faulty test, a misapplied test, or adverse test conditions (*e.g.*, high ambient noise levels).

Active participation in a hearing screening test is not always wanted or is even possible, *e.g.* when testing small children, or in crowded public spaces such as in a school. As outlined in Section 4.1, audiological methods can be classified as either *subjective* or as *objective* tests. A common subjective hearing test is the pure tone audiometry (PTA), where a tone with a fixed frequency is emitted through headphones into the patient's ear. The patient gives feedback, *e.g.*, by pressing a button if the tone can be heard. For subjective tests, multiple clinically validated smartphone apps are available [21]. Calibrated noise makers, which are intended to be used by medical professionals, have also been proposed as a low-cost solution [140].

Objective hearing tests do not require any feedback from the patient. Common methods are auditory brainstem response (ABR), where neural activity is measured with electrodes on the scalp in response to an acoustic stimulus. A low-cost ABR has also been proposed [142]; however, handling the electrodes and the longer measurement time is often prohibitive in first-level hearing screening procedures, especially in settings we are interested in. Another method involves measuring OAEs, which, in contrast to ABR, only requires placing a single acoustic probe in the ear canal. If normal hearing is present, an OAE test will only take a few seconds in most cases. While measuring OAEs has its caveats, it is often recommended in many hearing screening applications [123] and is particularly suitable in many situations, barring the high cost of OAE equipment and the need for trained medical personnel for operating them and administering the test.

4.2.1 Otoacoustic Emissions

OAEs are acoustic emissions, which are a result of active amplification processes in the cochlea located in the inner ear. These acoustic emissions travel backwards through the auditory system and can be observed as a minuscule acoustic signal in the ear canal. Since the the mid 70s, when David Kemp [81] was able to first measure this phenomenon, OAEs became common in audiological practice. At the same time, advances in technology have made the measurement of OAEs more practical. Today, commercially-available test equipment is often offered as dedicated handheld devices. Connected to such a device is an ear probe, which contains one or more speakers to generate a stimulus to evoke the OAEs, and also a microphone to record the

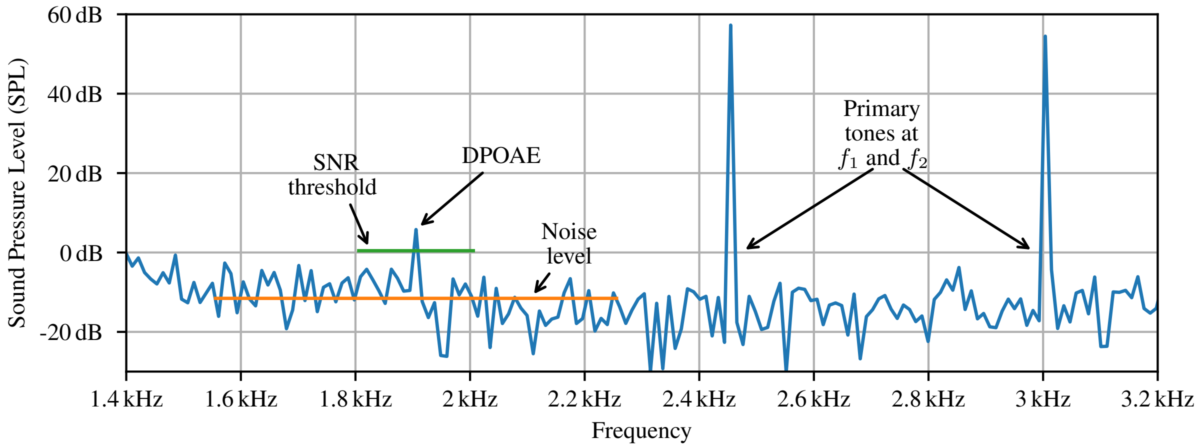


Figure 4.2: Example of a DPOAE recording at $3\,\mathrm{kHz}$ with the Samsung Tab A 10.1. The OAE response has an amplitude of $6\,\mathrm{dB\,SPL}$ and the noise floor is at $-12\,\mathrm{dB\,SPL}$ resulting in an SNR of $18\,\mathrm{dB}$.

resulting signal. The shape of the ear probe is similar to in-ear headphones. When measuring OAEs, the ear probe is fitted into the ear canal with a replaceable tip, to create a tight seal from the outside environment. This is needed to reduce ambient noise from disturbing the measurement, and also to keep the signal energy of the minuscule OAE signals inside the ear canal. The probe design and fit is crucial for measurement success. When placing the OAE ear probe in the patient's ear, attention must be paid to ensure a proper probe fit. As a part of this research, we also address this issue by designing ear probes equipped with sensors to provide live feedback on the correctness of the fit. But this problem is not the focus of this chapter.

Measurement protocols for OAE hearing screening are well established and in this work, we will focus on using these existing screening protocols on a *new platform*, *viz.,* an off-the-shelf smartphone instead of dedicated electronics platform. As discussed in Section 4.1, our goal is to enable smartphone-based objective hearing screening to increase the accessibility by lowering the cost and improving the usability by laypersons. The two most common OAE measurement protocols are distortion product OAE (DPOAE) and transient evoked OAE (TEOAE). We will briefly introduce both protocols, explaining how they are used for calculating the screening results. We rely on the details of these protocols in Section 4.5 that outlines our findings.

Distortion Product OAEs

A DPOAE response is evoked by stimulating the inner ear with two (primary) pure tones f_1 and f_2. If the cochlea is healthy, a characteristic tone at $2f_1 - f_2$ will be generated by it. Figure 4.2 shows an example recording in the frequency domain after a fast Fourier transform (FFT). To decide whether the recorded signal at $2f_1 - f_2$ is an actual OAE response or is noise, the noise level needs to be estimated by averaging the surrounding frequency bins. The ratio of $2f_1 - f_2$ and the estimated noise level is the signal to noise ratio (SNR). Only a SNR above a certain threshold will result in a "pass".

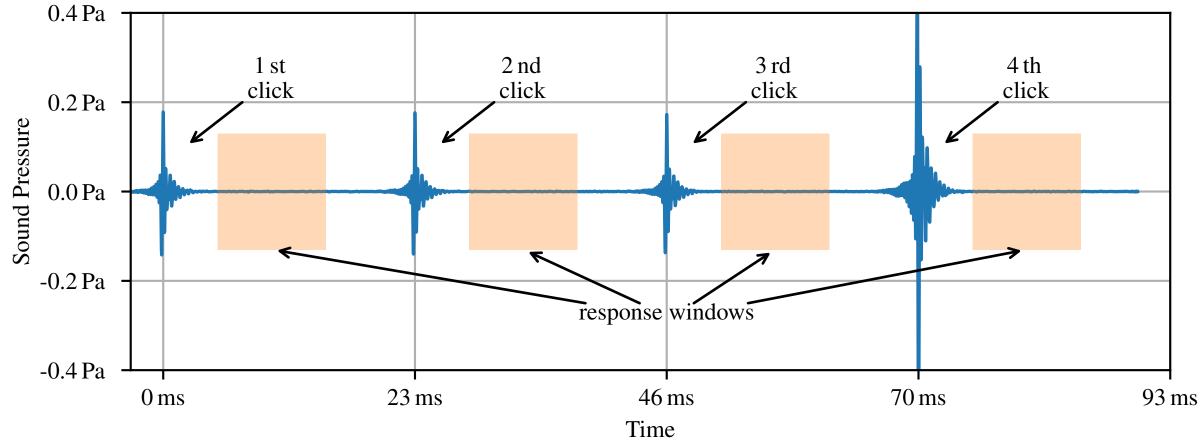
One DPOAE measurement will only test the cochlea at one specific frequency (f_2). Therefore, a small series of measurements at different frequencies must be conducted for a full screening test. The remaining base parameters for an individual measurement are: The frequency of f_1, which is usually defined close to the ratio $f_2/f_1 = 1.22$, and the level (sound pressure) of the primary tones which is set according to the *scissor paradigm* [96].

Transient-evoked OAEs

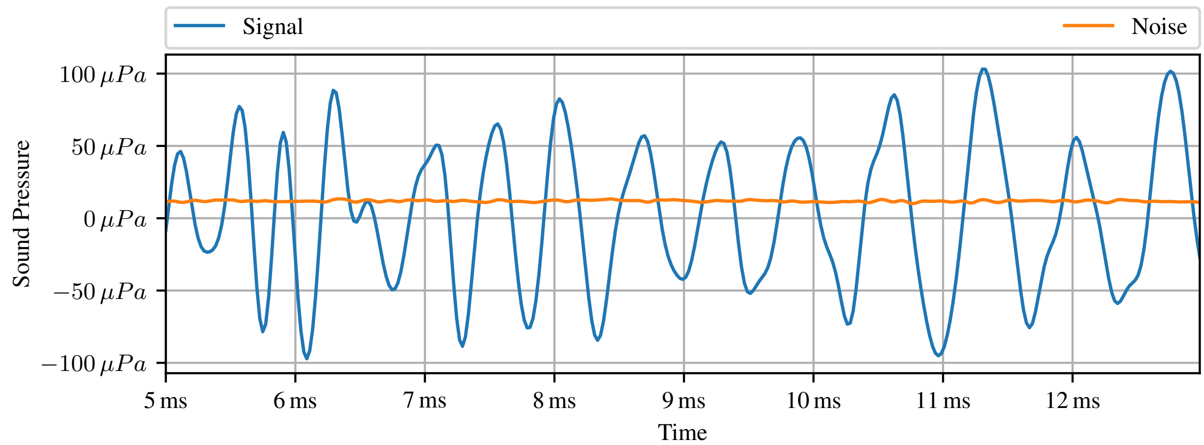
TEOAEs are excited by a stimulus consisting of a click of $80\,\mathrm{dB\ peSPL}$ (peak-equivalent sound pressure level [100]) in amplitude and of typically $100\,\mu\mathrm{s}$ duration. The response evoked in the inner ear by this broadband signal will be detectable in the ear canal after a few milliseconds. To distinguish the non-linear OAEs from the linear components and the echo of the stimulus, a non-linear measurement protocol with a series of clicks is used [83] as follows. Three clicks with normal amplitude are followed by a forth click with three times the amplitude and inverted polarity. Figure 4.3(a) shows a recorded response of this click sequence. By summing the responses of the four clicks, the linear components are canceled out and only the non-linear OAE, as well as the random noise, remain. Analogous to measuring DPOAEs, the noise floor and signal amplitude need to be quantified. Multiple responses are captured, which are then compared to each other. The signal component is approximated by taking the average of all responses, thus lowering the random noise. The noise is estimated by calculating a standard deviation value for each sample in time across all captured responses. Figure 4.3(b) shows the result of a normal hearing ear after 200 repeated click sequences. The OAE will arrive at the ear probe right after stimulus onset and is evaluated after the stimulus artifact has decayed. By taking the root mean square (RMS) of the extracted signal and the noise inside this window, we obtain single values for signal and noise levels. The SNR can now be calculated and compared to a threshold, in the same manner as with the DPOAE measurement to obtain a "pass" or a "refer". Due to the broadband nature of the stimulus, only one measurement is needed to test the cochlea for a wide range of frequencies.

Noise reduction

During all the measurements of OAEs, the amplitude of the signal of interest is very low. Noise, either from ambient sources, or the patient (*e.g.*, due to breathing or swallowing) or from the measurement system itself, is the most limiting parameter. Due to this, all components of a OAE measurement system are carefully selected to have a low noise floor at a reasonably high sensitivity. Since smartphones are not purpose built for OAE measurement but for general audio applications, their audio behavior – *e.g.,* noise levels – is very loosely defined. However, on all platforms the signal of interest is nevertheless often too close or below the noise floor. To lower the noise floor, the measurement is repeated, while keeping the stimuli constant, and averaging the recorded signal synchronously in the time domain. For DPOAEs, the averaging takes place over one FFT window size and for TEOAE, buffers are chosen such that they contain one click sequence. If N is the number of recorded buffers and the noise is normally distributed and uncorrelated, the noise level is lowered by the factor $1/\sqrt{N}$ [91]. In other words, there is a $3\,\mathrm{dB}$ reduction in the noise level with every doubling of the number of recorded buffers.



(a) Recording of the non-linear protocol click sequence, where the fourth click is inverted and has three times the amplitude. This four-click sequence is repeated multiple times, to lower the noise floor.



(b) Close-up of the averaged response window with extracted signal and noise. The high frequency components of the TEOAE arrive first. The response amplitude is more than $80\,\mathrm{dB}$ weaker compared to the stimulus.

Figure 4.3: Example of a TEOAE recording with the LG G5 SE smartphone.

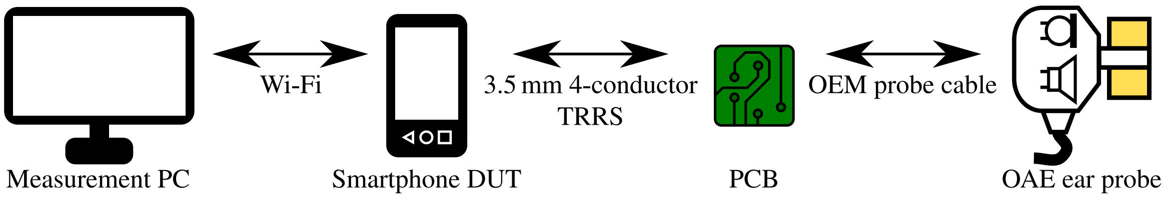


Figure 4.4: Measurement setup used in this work.

4.3 Smartphone-based System setup

This section discusses the basic technical requirements for OAE-based hearing screening and how we set up our smartphones. Any system for measuring OAEs and conducting a hearing screening test needs to at least consist of: An ear probe, one or more digital-to-analog converters (DACs) to drive the speakers in the ear probe, an analog-to-digital converter (ADC) to record the response, some kind of user interface to interact with the hearing test (*e.g.*, start/stop, display results), and a processing system to connect and drive all the components. In this chapter, we want to investigate whether all the components of such a system, except for the ear probe, could be replaced by a smartphone *by utilizing its headphone jack*. Figure 4.1 gives a schematic overview over such a system setup. Additionally, we want to be able to conduct the hearing screening test without any alteration of the phone itself, be it electronically or in software, (*e.g.*, by rooting the smartphone). This allows using a wide selection of phones and would require no special skills from the user, making the solution mass deployable.

We chose to base our investigation on Android smartphones, due to their high overall market share of over 80 % [148], the availability of low-cost models and the easy access to developer resources. However, the ecosystem of Android smartphones also poses one of the main challenges: Different manufacturers offer different models with many different software versions. In most cases, the manufacturer provides custom firmware and configuration for the hardware besides the Android operating system (OS). Hence, even if two smartphones share the same hardware platform and same patch level of the Android OS, they might still behave differently in terms of their audio characteristics, *e.g.*, due to different configurations of the audio amplifiers. For maximum generality, our work focuses on conducting hearing screening tests using only the APIs offered by Android to a conventional app.

4.3.1 Hardware and Software Setup

Figure 4.4 gives an overview of the hardware setup used in the experiments outlined in the following sections. A measurement personal computer (PC) controls the smartphone device under test (DUT) over a WiFi interface. In this configuration, the measurement PC runs all the processing software independently of the used smartphone. This enables us to also use other target devices, which we utilize in Section 4.5, to compare the smartphones with a commercially available OAE medical-grade measurement platform.

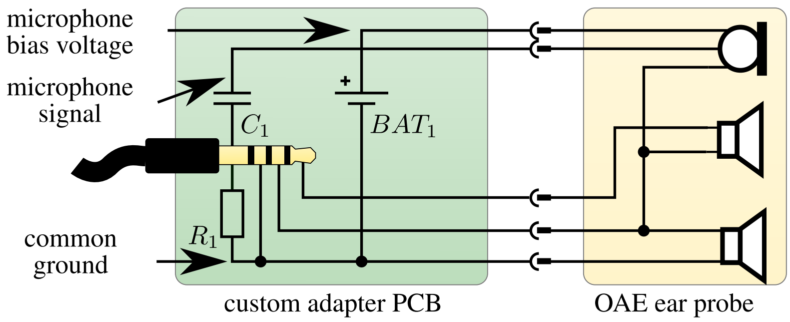


Figure 4.5: Schematic of the adapter PCB to connect OAE ear probes to a smartphone.

Table 4.1: Overview of the smartphone DUTs used in this chapter.

	Release	Android Version	Marketed as	Type
Fairphone FP3	Sep 2019	10	mid-range	smartphone
Huawei Nova	Oct 2016	7.0	mid-range	smartphone
Sony Xperia Z3+	May 2015	7.1.1	mid-range	smartphone
Google Nexus 7	Jul 2013	6.0.1	mid-range	phablet
LG G5 SE	Apr 2016	7.0	mid-range	smartphone
Motorola G4 Play	May 2016	7.1.1	budget	smartphone
Samsung Tab A 10.1	May 2016	8.1.0	budget	tablet

The smartphone is also connected with its $3.5\,\mathrm{mm}$ headphone jack to an OAE ear probe. For all measurements in this work, we used a commercially available OAE ear probe – model EP-DP produced by PATH MEDICAL GmbH [130]. To connect the OAE ear probe to the smartphone we built a custom adapter printed circuit board (PCB). Figure 4.5 shows the schematic of this PCB. This PCB will also handle the bias voltage for the OAE ear probe microphone. Android smartphones provide a microphone bias voltage between $1.8\,\mathrm{V}$ and $2.9\,\mathrm{V}$ [7]. However, the microphone of the used OAE ear probe requires a dedicated bias voltage and the microphone will also output a biased signal by itself. As a reliable and low-noise workaround for our experiments, we chose to put a capacitor (C_1) as a high-pass in the microphone signal path. The bias voltage for the microphone is provided by a CR2032 lithium coin cell battery. Some of the smartphones we used expected a certain direct current (DC) resistance for the probe to be correctly detected as headset, which is provided by $R_1 = 6.2\,\mathrm{k\Omega}$. The connection from our custom adapter PCB to the smartphone was provided by a regular $3.5\,\mathrm{mm}$ 4-conductor tip-ring-ring-sleeve (TRRS) connector cable.

4.3.2 Smartphone Configurations

We chose to use a number of different smartphones for our experiments. Table 4.1 lists all the smartphones used. All the phones had the most recent system update installed and all installed apps were up-to-date. The smartphone DUTs were loaded with our custom Android app. This app offers all relevant audio functionality to conduct a hearing test via the remote control interface on the network. Using this interface, the measurement PC is used to provide the buffers to be output on the speakers, and to collect the corresponding buffers with the recorded signal. Further, we can control volume levels and query other information from the smartphone. Having a non-mains connected setup for our experiments made the measurements more robust against some noise sources and also ensured the safety of the human subjects being tested.

Our app is built to use only standard calls to the Android API. According to the Android Compatibility Definition [7], only a small set of audio recording parameters must be supported by all devices, while many other settings are optional. All devices implementing audio recording, must support the "voice recognition" capture mode. In this mode, the device is expected to turn off noise reduction audio processing and automatic gain control (AGC), if present. Further, some specifications regarding a flat amplitude versus frequency response, linearity of amplitude changes and total harmonic distortion (THD) are given. To be able to easily compare results across all tested devices, the sampling parameter used in the Android API was set to $16\,\mathrm{bit}$ mono linear pulse-code modulation (LPCM) at a sampling rate of $44.100\,\mathrm{Hz}$, even though individual devices might support other modes, too. For the output, we used the same LPCM and sampling rate settings.

The latency in the audio stream between playback and recording is only very loosely specified. The devices must achieve an output latency (time between providing data to the Android API until measurable on headphone jack) and input latency (reverse of output latency) of maximum $500\,\mathrm{ms}$ each. However, the playback DACs and recording ADC are driven by the same clock source in the audio codec integrated circuit (IC) of the smartphone, so that there will be no drift between individual samples, just a fixed temporal offset once the audio streams are started. As a result, any temporal offset in the samples will only be noticeable as phase shift when doing frequency analysis, which is done in most of the measurements in this work. The only exception is the measurement of TEOAEs, where some analysis and windowing was done in the time domain. However, recovering the sample shift can be achieved by simply identifying the highest amplitude transient, which indicates a specific click in the non-linear protocol.

During an OAE measurement, the sound pressure of the stimuli must be set to a certain level. This was ensured in our work using two different means – the Android volume index and numerical attenuation. The Android "volume index" is a unitless integer number. Each increment of this number increases the gain of the audio stream relatively by an unknown step. This is usually implemented on the smartphone by setting the hardware gain in the audio codec IC. Generally, the volume index should be set as low as possible, such that the output amplifiers have the smallest gain and will produce as little distortion as possible. Further, volume adjustments can be achieved by setting the numerical amplitude of the digital signal sent to the Android API. The numerical attenuation should be as low as possible (as close to full scale as possible), to have the lowest volume index setting.

In summary, there are a number of characteristics in a smartphone that we need to know prior to conducting an OAE measurement. These characteristics distinguish different phones and determine their suitability as a platform for hearing screening.

4.4 Smartphone Characterization

When measuring OAEs, a linear and time-invariant (LTI) behavior of the measuring system is often assumed. Since the OAEs are non-linear, they can be distinguished from the stimuli and noise. This will only work as expected, if the whole signal path behaves linearly, from physical sound pressure to digital signal. Further, changes in the behavior during the measurement, for example if the AGC adapts the gain settings, will violate the assumption of time invariance.

The behavior of the OAE ear probe used in this work is well known. The ear probe will provide the interface from the sound pressure to electrical domain. The remaining translation from the electrical domain to the digital domain is provided by the smartphones' ADC. If this part of the signal path can be reasonably approximated as an LTI system, non-linear behavior in other parts of the system, namely the output path, can be compensated by forming a feedback loop with the input path.

In this section, we will identify the characteristics of the smartphone DUTs. The experiments are designed to quantify the input and output behavior of the audio subsystem of the smartphone DUTs and will focus on evaluating their LTI properties. Values given in $\mathrm{dB\,FS}$ (full scale) are referenced against the maximum digital signal value of the used LPCM encoding ($0\,\mathrm{dB\,FS} = 2^{15} - 1$). Sound pressure level (SPL) is a conventional unit for the pressure of sound and is referenced to approximately the threshold of human hearing at $1\,\mathrm{kHz}$ ($0\,\mathrm{dB\,SPL} = 20\,\mu\mathrm{Pa}$).

Two sets of characterization experiments were conducted. The first experiments electrically stimulate the smartphone DUTs inputs with an external voltage source to identify the behavior with as few external influences as possible. The second set of experiments were performed with an OAE ear probe, which was inserted into an ear simulator thus forming a loopback configuration.

4.4.1 Input Characterization with Electrical Sine Tones

In this experiment, we present the ADCs of the smartphone DUTs directly with an electrical signal. This allows us to rule out any interference from other components. The signals used are pure tone sine waves, generated with a National Instruments PXI-4461 sound module. We connected the analog output of the sound module to the microphone input on our adapter PCB. Then, each smartphone DUT was presented with a range of pure tone sine waves with the following frequencies and levels:

$$
\begin{aligned}
f &= \{0.5, 1, 2, 4, 8\}\,\mathrm{kHz} \\
L &= \{-32, -42, \dots, -112\}\,\mathrm{dB\,V}
\end{aligned}
$$

The levels were chosen with the nominal output sensitivity of the ear probe microphone of $-32\,\mathrm{dB\,V/Pa}$ as reference. At each of the resulting 45 points, 25 buffers of 8192 samples each ($\approx\ 5\,\mathrm{s}$) were recorded. The frequency transformed levels of the recorded signal were incoherently averaged across the buffers. This allowed us to measure signal levels below the dynamic range of the $16\,\mathrm{bit}$ LPCM and the noise floor of the microphone.

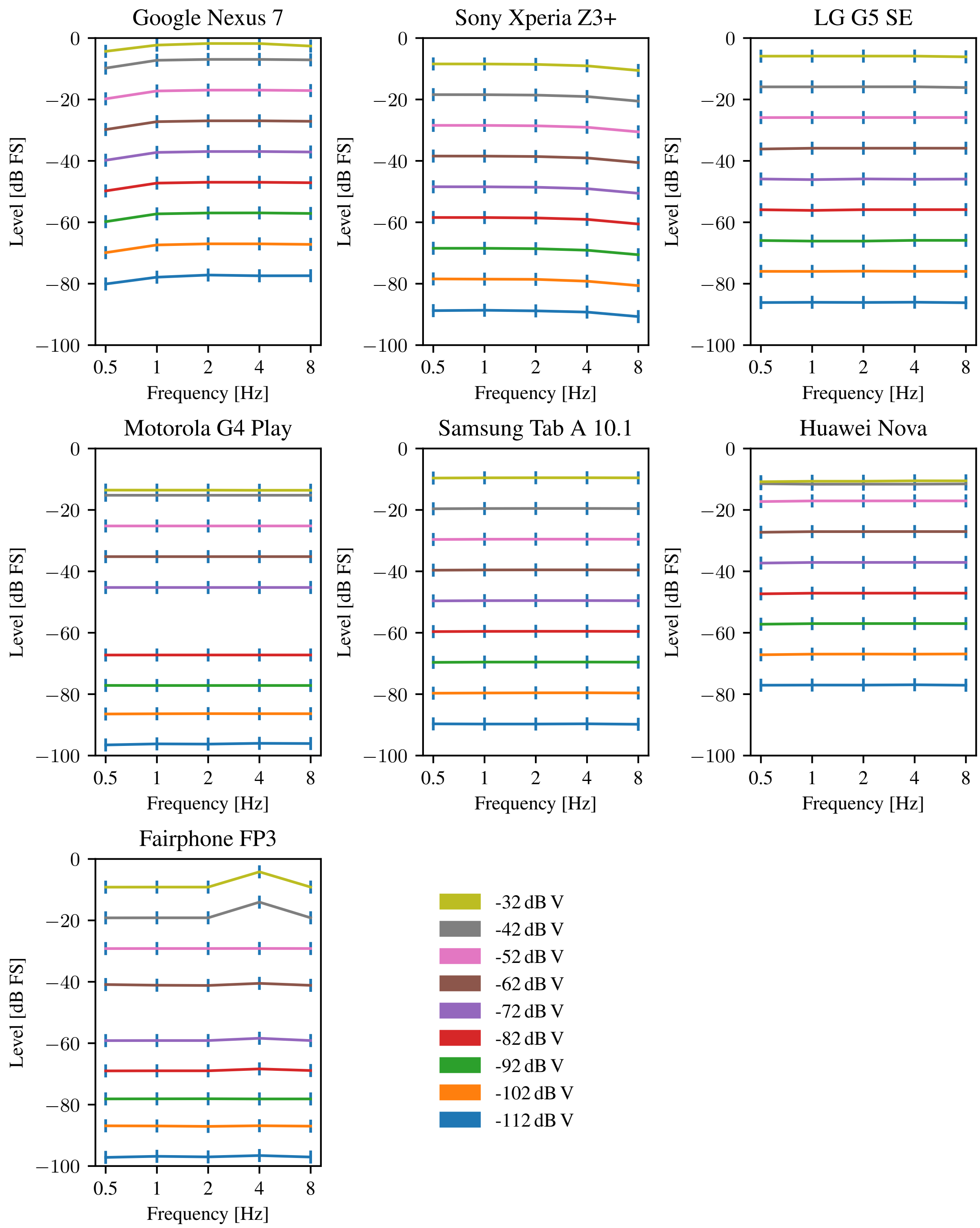


Figure 4.6: Measured digital signal amplitude after the microphone inputs of each smartphone DUT are sequentially stimulated with electrical sine waves of differing amplitude and frequency. The horizontal lines are only a visual aid, connecting each measurement of the same stimulus amplitude.

Two limitations of this setup have to be considered: First, the sensitivity of the microphone is specified with a spread of $\pm 3\,\mathrm{dB}$ between individual microphones at $1\,\mathrm{kHz}$. Second, the sound module used here has a very low impedance compared to the ear probe microphones, which is specified to be between $2.8\,\mathrm{k\Omega}$ and $6.8\,\mathrm{k\Omega}$. This is relevant due to the resistive load of the custom adapter PCB and the unknown impedance of each smartphone DUT. Combining these facts leads a certain error in absolute sensitivity. However, the results are very useful to compare the relative sensitivity levels (linearity). Further, it can be gauged from the results if the expected signal levels safely fit into the measurement range of each device. Finally, the recordings can be analyzed for their time behavior, i.e. how fast the signals settle and if they stay constant over time.

Input Linearity

Figure 4.6 shows the input signal level as measured by each DUT. The stimulus signal levels in this experiment are equally spaced. Ideally, for linear behavior, the recorded signal levels have the same equal spacing. This will generally be the case if the smartphones are configured to comply with the Android specification as discussed earlier. Especially in "voice recognition" mode, AGC and similar mechanisms must be disabled. However, with the Fairphone FP3 and Motorola G4 Play, different gains at different signal levels can be observed. This deficiency is very hard to compensate since it is not transparent through the Android API which gain level is currently used. Further, some of the devices show a “compression” at the highest signal levels of $-32\,\mathrm{dB\,V}$ and $-42\,\mathrm{dB\,V}$. In the case of the Google Nexus 7, the input is clipping. For the other affected DUTs, the input is indeed scaled down i.e., attenuated. While the expected signal levels during an OAE measurement are well below $-32\,\mathrm{dB\,V}$, the standard level for acoustic calibration ($94\,\mathrm{dB\,SPL}$) is expected at those levels.

Two phones, the Google Nexus 7 and Sony Xperia Z3+, show a frequency dependency of the sensitivity levels. A flat frequency response is not required for a linear system. However, it makes the calibration across the frequency range simpler, since only absolute offsets are needed. A close to ideal behavior can be seen with the LG G5 SE and Samsung Tab A 10.1.

Settling Behavior

The input stimulation in this experiment was started before the recording of the microphone input on the smartphone DUTs was started. Hence, changes in signal level at the beginning of the recordings are due to internal behaviors of the smartphone DUTs. Figure 4.7 shows the first $1.5\,\mathrm{s}$ at a stimulus level of $-32\,\mathrm{dB\,V}$ for each smartphone DUT. In all measurements, the recorded digital signal levels settled to a fixed value after an initial time of approximately $1\,\mathrm{s}$ to $2\,\mathrm{s}$. These seem to either be automatic fade-ins for glitch reduction, for example in the Samsung Tab A 10.1, or level adjustments of the AGC. This can be circumvented during an actual OAE measurement by simply discarding the first few seconds of the recording, which needs to be done anyway due to the unknown latency, as discussed earlier. Unfortunately, this settling delay at the beginning of each recording leads to an increase of the overall measurement time, which is one quality metric for any OAE hearing screening system.

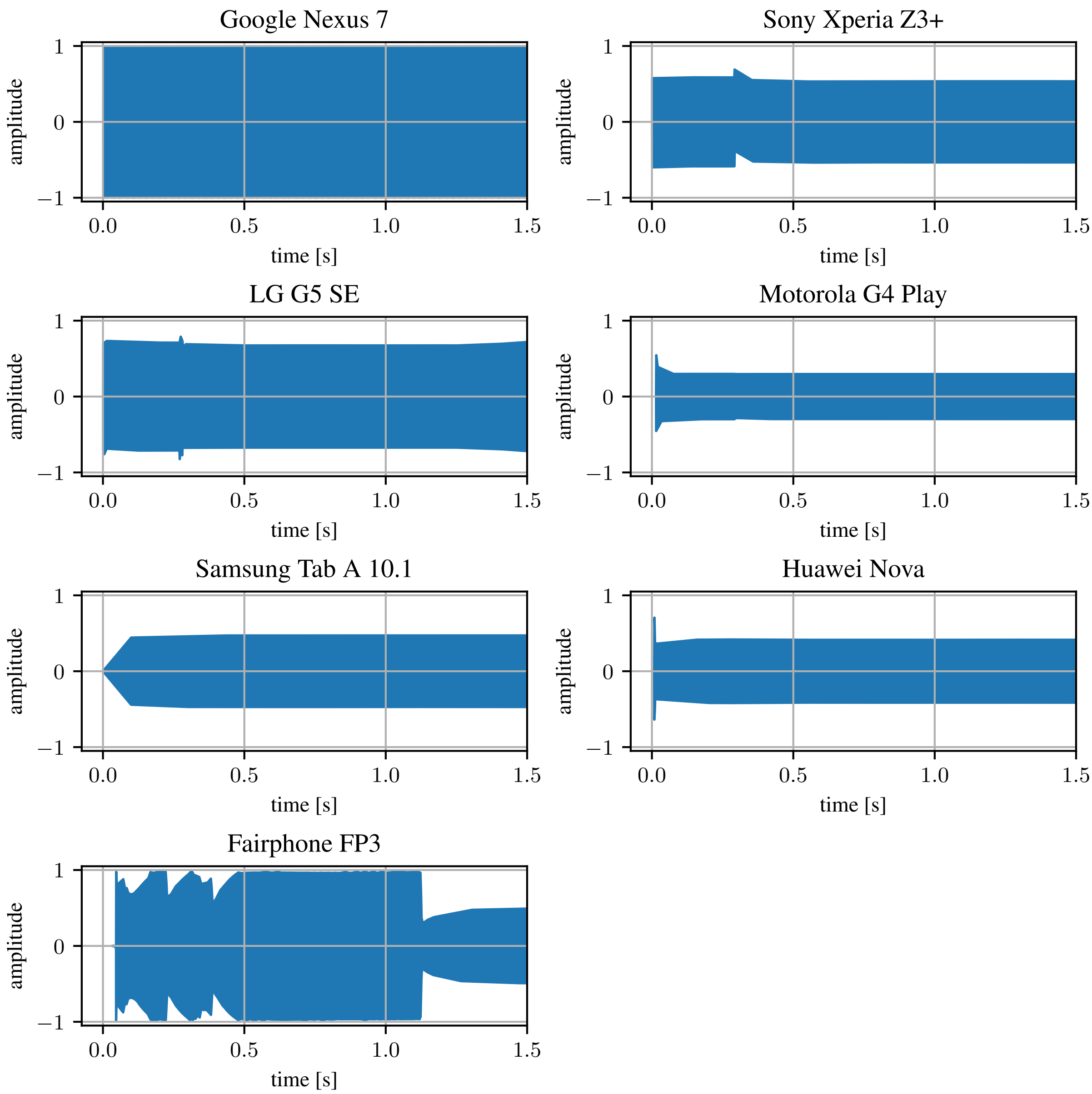


Figure 4.7: The smartphone DUTs microphone inputs are stimulated with a sine wave of $-32\,\mathrm{dB\,V}$ at $1\,\mathrm{kHz}$. The figure shows the normalized amplitude of the beginning of the recorded values. All seven smartphone DUTs show a different settling behavior and it takes $1.5\,\mathrm{s}$ for all of them to settle completely. In some cases, significantly longer settling times were observed.

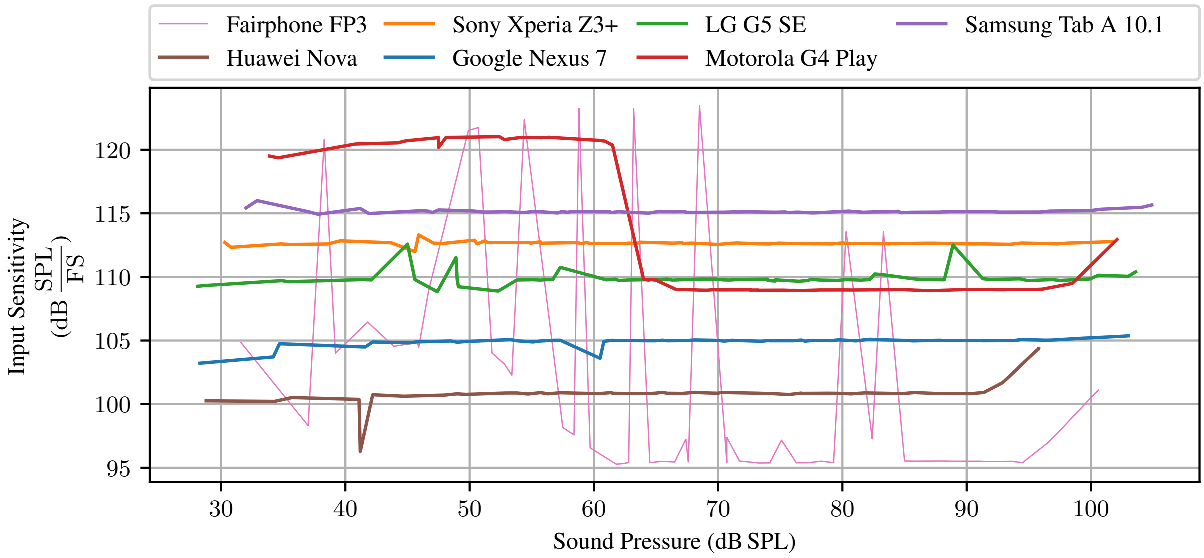


Figure 4.8: Input sensitivity dependent on the sound pressure. Measured in the AEC 304 ear simulator with $1\,\mathrm{kHz}$ pure tones output by the smartphone DUT.

4.4.2 Input/Output Pure Tone Measurements

In this experiment, the smartphone DUTs were connected to the OAE ear probe, which was inserted into a Larson Davis AEC 304 ear simulator [115]. This ear simulator resembles the acoustic properties of the human ear canal and has a microphone at the "ear drum". In this experiment, a pure tone sine wave was generated, which was output by the smartphone DUTs DAC into the speakers in the ear probe. The sound pressure signal was captured by the ear simulator microphone, which was connected to a Larson Davis System 824 sound level meter (SLM) [164]. The calibrated SLM was then queried on its digital interface to read the absolute sound pressure, the frequency and a corresponding THD value at the ear simulator "ear drum". Additionally, the smartphone DUT recorded the probe microphone and the digital signal level was calculated. The following parameters were tested, resulting in 300 individual measurement per DUT:

$$\begin{aligned} f &= \{0.5, 1, 2, 4, 8\}\,\mathrm{kHz} \\ volume\ index &= \{1 \dots 15\} \\ L_{num} &= \{0, -20\}\,\mathrm{dB\,FS} \\ stereo\ channel &= \{\mathrm{L}, \mathrm{R}\} \end{aligned}$$

L_{num} is the numerical output level. The parameters where chosen to receive a full frequency and amplitude response in the relevant range.

Input Sensitivity

In this section, we evaluate the input for linearity across differing levels of sound pressure and an absolute sensitivity value for later use in the OAE experiments in Section 4.5.

Table 4.2: Overview of the smartphone DUTs characterization results based on the output pure tone measurements. The input sensitivity is measured at $1\,\mathrm{kHz}$ and the numeric gain error is given for a $20\,\mathrm{dB}$ difference in amplitude.

	Input sensitivity		Numeric gain error	
	Mean ($\mathrm{dB}\frac{\mathrm{SPL}}{\mathrm{FS}}$)	SD (dB)	Mean (dB)	SD (dB)
Fairphone FP3	108.9	9.89	1.14	1.81
Huawei Nova	100.9	0.04	0.30	0.35
Sony Xperia Z3+	112.7	0.07	−0.17	0.35
Google Nexus 7	105.0	0.26	0.45	0.35
LG G5 SE	109.8	0.25	1.69	1.22
Motorola G4 Play	114.9	5.61	0.35	0.34
Samsung Tab A 10.1	115.1	0.04	0.23	0.33

At low frequencies, e.g. at $1\,\mathrm{kHz}$, the sound pressure distribution is still fairly uniform inside the ear simulator and ear canals [152]. The SLM provides absolute sound pressure values, which can be used to establish the input sensitivity of the smartphone DUT with our OAE ear probe connected. By taking the ratio of the levels of the SLM (in $\mathrm{dB\,SPL}$) and the smartphone DUT (in $\mathrm{dB\,FS}$) the input sensitivity can be calculated as

$$S_{input\ smartphone} = L_{SLM}/L_{input\ smartphone}.$$

This results in one sensitivity value per measurement in this experiment. Figure 4.8 shows the results depending on the sound pressure in the ear simulator as measured by the SLM. If no AGC is active, the response should ideally be a horizontal line. This would indicate that the digital values are linear to the applied sound pressure. The response of the Motorola G4 Play was problematic, where a jump was observed, and the Fairphone FP 3 had an erratic behavior. The rising “tails” at high sound pressures were found to be either clipping or compressed and were far beyond the sound pressures used when measuring OAEs. Table 4.2 shows the resulting sensitivity for each smartphone DUT when only using values taken at $1\,\mathrm{kHz}$ and between $50\,\mathrm{dB\,SPL}$ and $80\,\mathrm{dB\,SPL}$. These values were used as calibration offsets in the actual OAE measurements reported in Section 4.5. The sound pressure range was chosen such that the values are far enough apart from the noise floor, but not high enough for clipping and other distortions being a problem. At least 20 measurements per smartphone DUT fell into these criteria and were used for calculating the average and standard deviation values.

Numeric Gain Error

Here, we evaluate whether a change in the numerical output level results in a corresponding proportional change in sound pressure output in the ear simulator. Each measurement in this experiment was done with a numerical amplitude of $0\,\mathrm{dB\,FS}$ and was repeated with $-20\,\mathrm{dB\,FS}$.

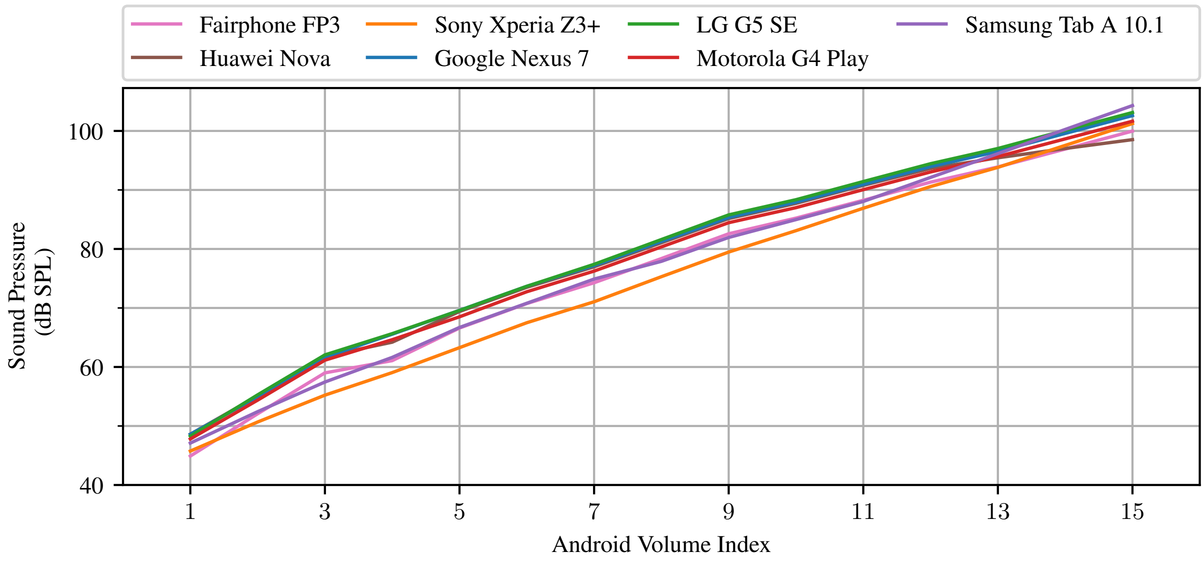


Figure 4.9: Average sound pressure dependent on the Android volume index. Measured in the AEC 304 ear simulator with 1 kHz pure tones output by the smartphone DUT.

Table 4.2 summarizes the resulting error when comparing each of these two associated measurements. Only measurements where both sound pressure readings of the SLM were between 50 dB SPL and 80 dB SPL are used for the average and standard deviation calculation. The resulting sound pressure at the ear simulator microphone should change by the same ratio as in the numerical amplitudes. It can be seen that most smartphone DUTs have a low enough error so that changing the output amplitude can directly and proportionally be achieved with the numerical amplitude. While the LG G5 SE and the Fairphone FP 3 exhibit a distinctly above average error of the output amplitudes, this can be compensated by using the ear probe microphone as feedback source to adjust the levels during the in-ear calibration (IEC).

Volume Index Gain

The second method of controlling the output gain is setting the Android volume index. As discussed in Section 4.3, we need to set the Android volume index as low as possible. The amount of increase in sound pressure for each step is not specified in the Android Compatibility Definition. For this reason, we analyzed the relationship between sound pressure increase and the Android volume index. Figure 4.9 shows the resulting sound pressure levels read by the SLM in the ear simulator for each volume index setting at 1 kHz. The figure shows that the absolute sound pressure exerted is within a fairly narrow band of 6 dB for each volume index setting across all smartphone DUTs.

Discussion

The results of this experiment show that all smartphone DUTs are able to output the required stimuli levels in a reproducible manner. Further, we now know the “volume index” behavior for each individual device and have values for the input sensitivity at 1 kHz with an actual ear probe connected. However, noticable problems exist for some devices in the input path, which excludes them from usage in the OAE experiments. These include the Fairphone FP3 and the Motorola G4 Play.

For the actual OAE measurements, which will be presented in the next section, the full frequency response, i.e. the calibration, of the ear probe microphone was obtained in accordance with techniques outlined in Section 2.4.3. This frequency response was then offset with each smartphone DUTs individual input sensitivity at $1\,\mathrm{kHz}$. Knowing this relation is necessary to set and monitor the amplitudes of the stimuli during the OAE measurements. This IEC is performed after each probe insertion into an ear and prior to every OAE measurement. Details on the IEC can be found in Section 2.4.4.

4.5 OAE Experiments

In the previous section, we identified the basic characteristics of the smartphone DUT audio subsystem. However, to verify that the tested smartphone DUTs are indeed able to measure OAEs, a small study was conducted in which DPOAEs and TEOAEs were measured in human ears. Two smartphones – the Motorola G4 Play and the Fairphone FP 3 – where excluded from all following measurements, since their input behavior was unsuitable. We measured five adults aged 25-35, resulting in measurements in 10 ears. All measurements were preceded with an OAE measurement using a commercially available device (PATH MEDICAL Sentiero [130]), which is referenced as the "*Reference Device*" in this section. Further a second Path Sentiero with a modified firmware was used, referenced as the "*Research Device*", that can be remotely controlled in the same way as the smartphone DUTs.

All measurements on human ears were preceded with a measurement in the AEC 304 ear simulator. Since the ear simulator does not exhibit OAEs, it will provide data for true positive hearing loss (sensitivity). As such, these measurements should result in a "refer". However, the recordings with the Huawei Nova in the ear simulator contained extremely high distortion levels in the ear simulator. So it was also not used with actual human ears. Thus, the following experiments were each repeated with only the four remaining smartphone DUTs, the research device, and the reference device.

The measurement procedure for each ear was the following. After inserting the ear probe into the ear canal, a linear chirp was emitted sequentially on both the ear probe speakers and the response was recorded (in-ear calibration). This frequency response was used to manually determine the quality of the probe fit and the symmetry of the speakers. For DPOAE, the frequency response was directly used to set the output gain (numeric and Android volume index), such that the primary stimuli tones were measurable at the probe microphone at a desired level. However, this direct feedback in-ear calibration may result in inadequate stimuli levels at the ear drum due to uneven sound pressure at higher frequencies [28], [152], see Section 2.4.4 for more details. For TEOAE, a low amplitude click was emitted into the ear canal and the necessary gain was calculated from the response. To complete measurement of one ear took approximately five minutes per device. All devices were measured in each ear in direct succession, if possible without removing/readjusting the ear probe.

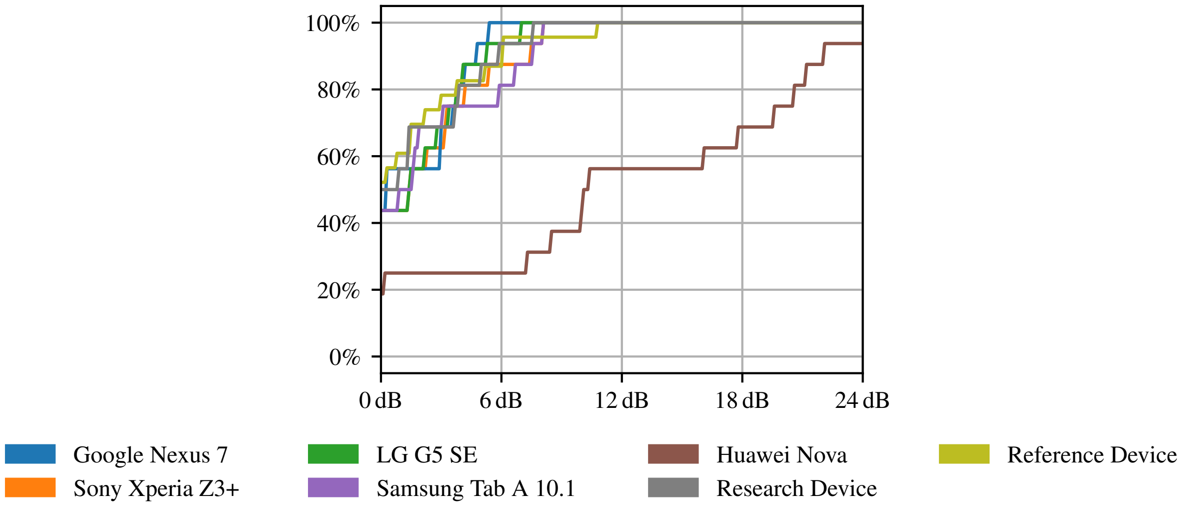


Figure 4.10: Sensitivity of the DPOAE measurements, averaged between $1.5\,\mathrm{kHz}$ and $4\,\mathrm{kHz}$, dependent on the SNR threshold.

4.5.1 Distortion product OAE (DPOAE)

Recordings were taken for 10 seconds at

$$f_2 = \{1, 1.5, 2, 3, 4, 6\}\,\mathrm{kHz},$$
$$L_2 = \{35, 45, 55, 65\}\,\mathrm{dB\,SPL}$$

resulting in 24 measurements per device per ear. The other parameters are $f_1 = f_2/1.22$ and L_1 was set with the scissor paradigm $L_1 = 0.4 \times L_2 + 39\,\mathrm{dB\,SPL}$ [96]. These tested frequencies and levels are common DPOAE hearing screening parameters.

Figure 4.10 shows the sensitivity dependency of the SNR threshold for each DUT. These measurements were done in the passive ear simulator, where no OAEs were present. Thus, all of these measurements should result in a “refer”, *e.g.*, they should remain below the chosen threshold. In this data, almost no correlation to stimuli frequency or stimuli level was found. With the exception of the Huawei Nova, all DUTs performed similarly well. Figure 4.11 shows the specificity, *i.e.*, the ratio of measurements resulting in a “pass” when the hearing is actually normal at a common screening stimuli level of $L_2 = 55\,\mathrm{dB\,SPL}$. Here, a connection to the stimuli parameters exists. The low specificity at $1\,\mathrm{kHz}$ is a limitation of DPOAEs, which are often difficult to measure at low frequencies. Further, at higher frequencies, especially at $6\,\mathrm{kHz}$, the “pass” rate drops, too. This is unlikely a shortcoming of the smartphone DUTs since the research device also degrades, but not the reference device. More likely, the stimuli was not at the correct level. However, results at the typical DPOAE hearing screening frequencies, between $1.5\,\mathrm{kHz}$ to $4\,\mathrm{kHz}$, were promising.

Selecting a “pass”/“refer” decision threshold on the SNR will therefore either result in better sensitivity or better specificity. Since a single measurement will only test one frequency in the cochlea, an overall “pass” is usually defined by passing at least $3/4$ or even $4/4$ frequencies out of $f_2 = \{1.5, 2, 3, 4\}\mathrm{kHz}$. Table 4.3 shows the number of passing ears when applying these criteria and also at two common SNR thresholds of $9\,\mathrm{dB}$ and $12\,\mathrm{dB}$ respectively.

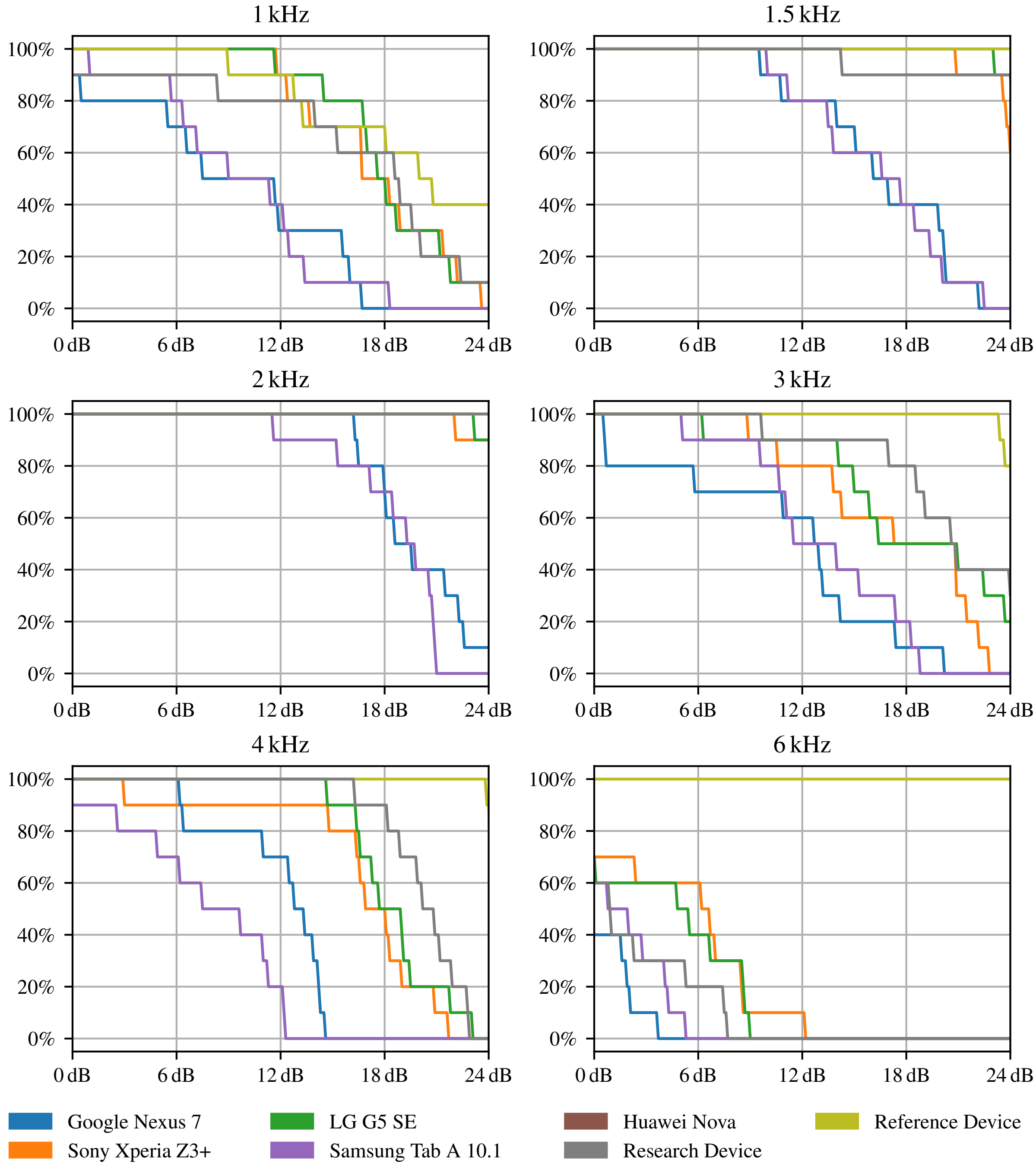


Figure 4.11: Specificity of the DPOAE measurements dependent on the SNR threshold for each DUT at $55\,\mathrm{dB\,SPL}$ stimulus.

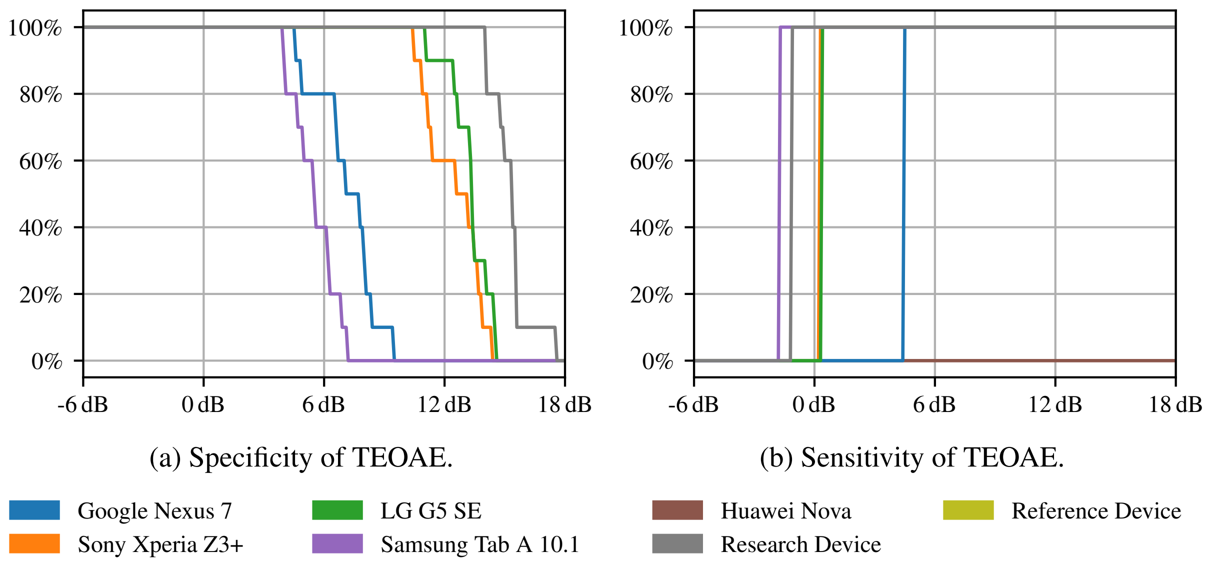


Figure 4.12: Overview of the TEOAE measurement results. Sensitivity data was obtained in the ear simulator. The data is shown dependent on the SNR threshold.

4.5.2 Transient evoked OAE (TEOAE)

The stimulus level for TEOAE was set to 80 dB peSPL, a very common stimulus level for TEOAE hearing screening, and 200 non-linear click sequences were recorded per measurement, resulting in approximately 19 s of recording time for each smartphone DUT. Table 4.3 shows the average noise floor for each device as well as the measured SNR in the ear simulator. Again, the Huawei Nova, and also to a lesser extent the Google Nexus 7, showed an increased SNR, which means that some signal was picked up when there should have been none. Figure 4.12(a) shows the specificity, dependent on the SNR threshold. The reference device is not shown, since it does not output the SNR for TEOAE measurements, but all measurements resulted in a "pass" on that device.

4.5.3 Results and Implications

All the four smartphones used in this trial did not show an increased response in the ear simulator, neither with DPOAE nor TEOAE. This implies a good performance in terms of sensitivity. The results summarized in Table 4.3 show how many of the human ears could pass a screening test, when the criterion given in each column was applied. It can be seen that the performance of the LG G5 SE smartphone is almost as good as the research device.

While the performance of all smartphone DUTs was below that of the dedicated OAE screening device, the four qualified smartphones were still able to detect the OAE signals eventually after a longer measurement duration. Further, it should be considered that our current OAE measurement software is target agnostic and was not optimized for any single device. This is in sharp contrast to the reference device, which had a target-platform specific implementation.

Table 4.3: Results of the OAE measurements with 10 normal hearing human ears. Each column shows, how many ears (out of 10) would have passed if the given SNR threshold was applied to the measurements. For DPOAE, the results are also shown if at least 3/4 or 4/4 frequencies passed.

	DPOAE				TEOAE		
	$3/4\ f_2$		$4/4\ f_2$				
	$9\,\mathrm{dB}$	$12\,\mathrm{dB}$	$9\,\mathrm{dB}$	$12\,\mathrm{dB}$	$6\,\mathrm{dB}$	$9\,\mathrm{dB}$	$12\,\mathrm{dB}$
Huawei Nova							
Sony Xperia Z3+	10	8	10	7	10	10	6
Google Nexus 7	10	5	8	3	8	1	0
LG G5 SE	10	9	10	9	10	10	9
Samsung Tab A 10.1	9	5	5	0	4	0	0
Research Device	10	10	10	9	10	10	10

4.6 Chapter Summary

In this chapter, we have, for the first time, demonstrated the feasibility of a smartphone-based *objective* hearing screening test. We were able to conduct our evaluations without any hardware or software modification to the phones, but by using only the standard Android API. Out of the seven smartphones we tested, we found that two (Fairphone FP 3, Motorola G4 Play) had unsuitable input behavior and one (Huawei Nova) produced unacceptable levels of distortion, making all three of them unsuitable. With the remaining four phones, we were able to conduct an OAE hearing screening trial with promising results.

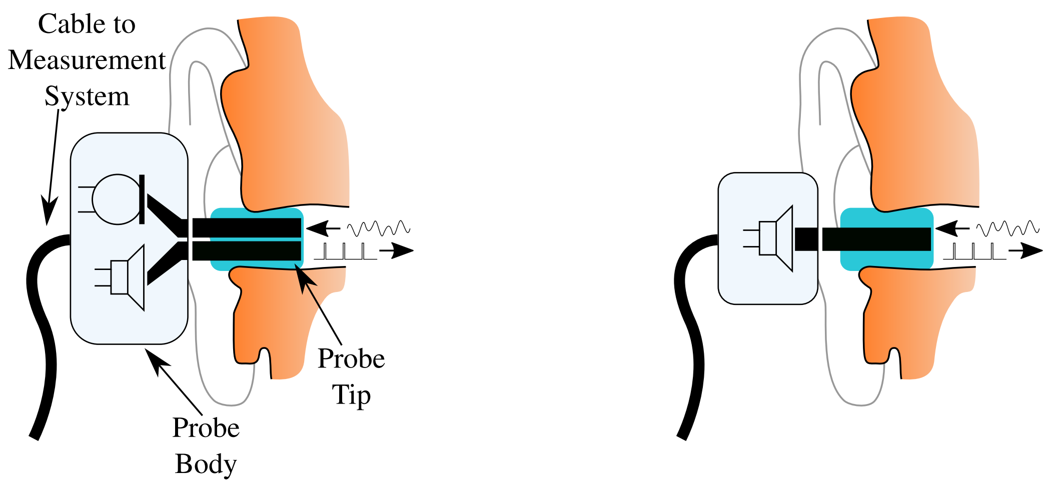
Our original vision of providing potential users with an ear probe and an app so that they can user their own phone might not be tenable due to the high percentage of unsuitable phones. However, providing a curated list of smartphones or providing a bundle including the smartphone and the ear probe are still viable approaches that meet our requirements, *viz.*, a mass-deployable hearing screening test that is low-cost, fast, and does not need trained medical personnel. Shipping a phone with app + headsets is currently the practice for *subjective* smartphone-based hearing tests [156]. Hence, our solution provides an *additional modality* of screening that does not require any explicit interaction with the subject. Even for providing a full solution with a smartphone and ear probe bundle, the question of manufacturing variations across two phones of the same make and model – thereby having different audio characteristics – remains open. The microphone input path characteristics are probably not closely controlled by smartphone manufacturers to the degree they control other features. This issue needs further investigation.

Finally, this work only investigated the technical feasibility of using smartphones for objective hearing screening. To further improve usability for laypersons and *e.g.*, provide feedback on probe fit, we also plan to explore the various options that smartphones today offer in terms of connectivity and user interaction.

5

Single Speaker-based OAE Probes

The previous two chapters focused on the device architecture of otoacoustic emission (OAE) measurement systems. However, the OAE ear probe is at least equally important to the performance of such a system. At the same time, OAE ear probes present a significant share of the overall complexity and cost. In this chapter, a novel OAE ear probe is presented that is considerably less complex but more robust, compared to a common ear probe.



(a) Typical TEOAE probe

(b) Proposed TEOAE probe

Figure 5.1: Schematic overview of a typical TEOAE ear probe and the proposed TEOAE ear probe.

5.1 Introduction

Hearing impairment is one of the most widespread disabilities world wide [33]. It can have a vast personal impact on communication, well-being, quality of life and health. Especially for neonates and small children, proper hearing is important for speech development. In many regions around the world, a universal neonatal hearing screening program has been implemented. Despite these efforts, there still is a lack of coverage, especially in developing countries and even rural areas of newly industrialized countries, such as India [113]. In these regions, childbirth often does not take place in maternity hospitals, but at home, where access to objective hearing screening tests is limited. Further, skilled maternal and newborn health workers are also often unavailable [169]. In many cases, detection of the hearing loss comes too late, although treatment is possible and available. Another prevalent form of hearing loss is noise-induced hearing loss (NIHL) [65]. In many situations, the affected person will not immediately be aware of the hearing loss. Increasing the availability of low-cost and easy to use tests would allow for more widespread screening.

The most common objective hearing screening test is based on OAEs, which are active emissions from the inner ear. Figure 5.1(a) shows a typical configuration of an ear probe used in such tests. A built-in speaker is used to emit a specific stimulus and a microphone will record the response. We intend to provide a hearing screening test based on OAEs for a health worker or even at home, which is similar to using a medical thermometer. To achieve this, both cost as well as ease-of-use are factors that need to be addressed.

In this work, we present a simplified OAE probe, which only consists of a single transducer, shown in Figure 5.1(b). With this simplification, the construction of the probe will be significantly less complex. While fewer components are needed and fewer electrical connections need to be made, we see the advantages mostly in the mechanical buildup: The probe tip needs fewer details, since only one acoustic channel is needed. This allows for a more robust construction, which may be less prone to mishandling and clogging with cerumen. Our proposed probe may cost US $10, compared to the several hundred dollars retail price of commercially available probes, which are usually hand assembled. The cost savings may be achieved by utilizing existing mass-manufacturing processes, which already exist for in-ear headphones.

In the following chapter, we highlight related work that also intents to provide more ubiquitous hearing screening. Afterwards, we give a basic introduction to hearing screening with OAEs. Then we present how we constructed and characterized our prototype probes. Finally, we demonstrate a proof of concept with a complete OAE measurement.

5.2 Related Work

The need for hearing screening is widely accepted and is reflected, for example, in universal neonatal hearing screening. The problem of unavailability of hearing screening, due to cost, lack of trained personnel or unawareness has also been addressed before.

As smartphones are ubiquitous for many people around the world, their use in low-cost medical applications became of interest. These devices are highly accessible and often include powerful audio interfaces. This allows self administered hearing screening tests utilizing smartphones and any in-ear or over-ear headphones. Na et al. [120] presented a subjective test with pure tone audiometry and correction of environmental noise levels. This test requires a calibration of the sensitivity of the smartphone used. A subjective smartphone-based digit-in-noise test was demonstrated by Potgieter et al. [134], which has been successfully validated [107].

For hearing screening of neonates, calibrated noise makers have been investigated by Ramesh et al. [140]. These devices are intended to be used by medical practitioners and administering the test requires a certain amount of training.

Low-cost devices based on auditory brainstem response (ABR) have also been considered by Singh et al. [142]. The advantage of ABR-based screening is the full coverage of the auditory system. However, placing and cleaning electrodes may prove difficult in practice and an ABR test usually takes longer to complete, compared to an OAE-based test.

With our novel probe design, we intent to close the gap in the unavailability of low-cost hearing tests, based on OAEs, which is an objective and clinically well known method.

5.3 Hearing Screening with OAEs

Hearing screening may be categorized as subjective and objective hearing tests. A common subjective test is pure tone audiometry. This method requires comparatively little equipment and can identify the hearing thresholds well. However, it requires active participation of the patient during the examination. In contrast, a number of objective hearing tests are used in medical practice today that do not require any interaction with the patient. The analysis of OAEs is probably the most widely used objective hearing screening test. Hearing screening tests, in contrast to hearing diagnostics, usually do not give full results, but only “pass” or “refer”: Hearing level is adequate or refer to a medical professional for further diagnosis.

Figure 5.2 shows an overview of the human peripheral auditory system. The inner ear is receptive to different frequencies at different locations on the basilar membrane. Close to the oval window, at the base of the cochlea, high frequencies will be detected and lower frequencies are detected closer to the apex. An active process, the cochlear amplifier, will amplify the acoustic signals on the basilar membrane, with the outer hair cell (OHC) being the main component. Those active processes may by themselves emit an acoustic signal. This signal will then travel backwards through the cochlea and middle ear into the ear canal and can there be observed as an OAE. OAEs are categorized into spontaneous and evoked OAEs, where evoked OAEs are stimulated with an external acoustic signal. In diagnostics and research, many types of OAEs are used. However, in hearing screening only two evoked OAE procedures are commonly used: Distortion product OAEs (DPOAEs) and transient evoked OAEs (TEOAEs).

While both procedures can be used for screening, we exploit the temporal separation of stimulus and response in TEOAEs for our probe design. Here, the stimulus is a transient, often referred to as click, of $80\,\mu s$ to $100\,\mu s$ duration. The clicks are presented as a sequence of three clicks of positive polarity followed by a click of an inverse polarity with an intensity three times higher than the positive clicks [83]. The stimulus intensity is set such that the TEOAE recordings originate from saturated cochlear generators, i.e., around $85\,\mathrm{dB\,SPL}$. The TEOAE will be measurable in the ear canal right after the click onset of the stimulus. Due to

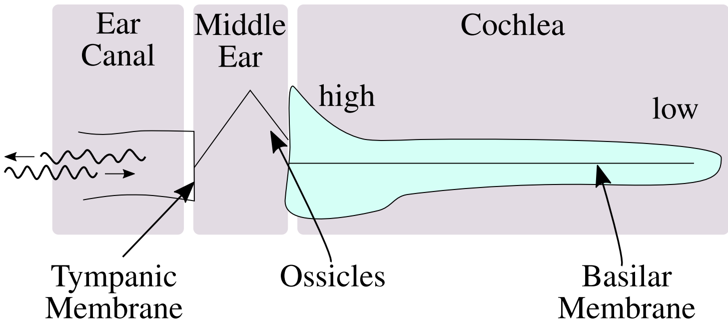


Figure 5.2: Schematic overview of the peripheral auditory system, with the cochlea “rolled out”.

the frequency-location dependency in the inner ear, the high frequency response will arrive first. Typically, a window of up to $20\,\mathrm{ms}$ after the click is recorded and analyzed.

Figure 5.1(a) shows a typical probe used for measuring TEOAEs. A speaker is used to emit the clicks. The response is recorded shortly after by means of a sensitive electret microphone. Both transducers need to be connected to the ear canal by separate acoustic channels.

Since the TEOAEs represent the OHC pulse response along the basilar membrane, the response occurs according to the delay of the basilar membrane. By exploiting this delay, we propose our new probe, which can be seen in Figure 5.1(b). This probe will be much simpler in mechanical construction and will be easier to assemble, thus substantially reducing manufacturing cost. Due to the much simpler probe tip, consisting of only one acoustic channel, the mechanic interface for the replaceable probe tips will need much less complexity. This will make replacing probe tips easier and the consumables will cost less.

The main challenge in our proposed probe design is the much lower sensitivity when recording from a speaker, compared to a microphone. Since the OAE signal is extremely weak, a dedicated microphone is usually considered indispensable.

5.4 Prototype Probe Design

To evaluate our proposed probe design, we built several prototypes. The design was oriented on the earlier mentioned goals of reducing cost and easy handling.

5.4.1 Objectives

For achieving the overall goal of providing a low-cost probe design, the components must be low cost. However, the construction and manufacturing process must be low-cost as well. Therefore, the probes should be kept as simple as possible. The selection of speakers for the work in this chapter was based on physical size, specified frequency behavior, part cost, mounting options and sound port layout. The overall performance of TEOAE probes is dominated by acoustic properties which are largely dependent on the mechanical design. A well performing probe should have a flat frequency response for emitting sound and recording. It must seal the ear-

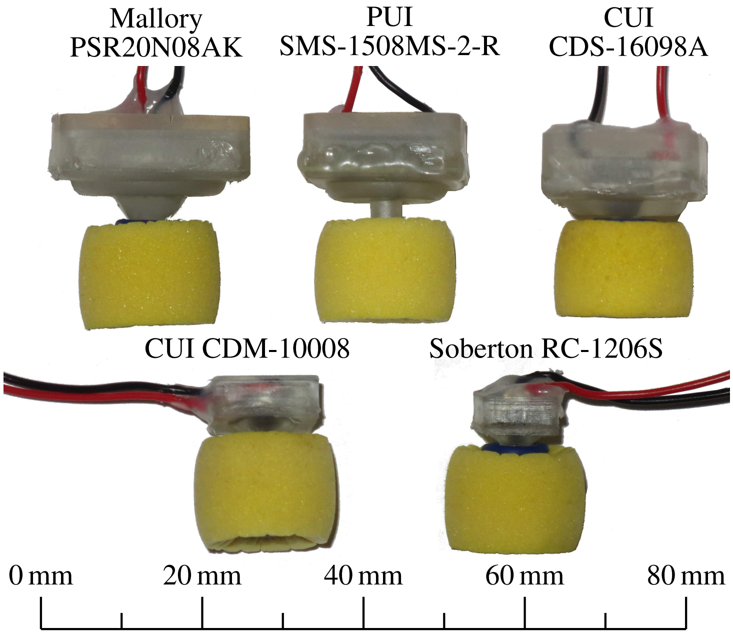


Figure 5.3: Picture of the prototype probes.

canal so that as much sound energy, coming from the tympanic membrane, can be captured by the probe. Especially low frequencies will otherwise be lost. A good seal from the ear canal to the environment is also necessary so that as little outside sound as possible will interfere with the measurement. This seal is usually implemented with a soft probe tip, which presses against the ear canal. Consequently, a good probe design has to fulfill other requirements besides the acoustical properties. The probe tip needs to be easily replaceable, since it should be disposed after measuring each patient. As mentioned above, hearing screening in infants and newborns is of particular significance, so the probe and probe tip need to be small enough to fit into a newborn's ear. Achieving the two last mentioned objectives is expected to be much easier with a single speaker probe, since designing a small probe with only one component is much simpler.

5.4.2 Approach

All prototype probes presented and measured in this chapter where manufactured using a stereolithography (SLA) 3D printer. This process allows for very detailed features and a good surface quality. Overall five prototype probes where built, using five different speakers. The design of our prototype probes aimed at keeping the parts and assembly as uncomplicated as possible. Figure 5.4 shows an exploded-view drawing of one of the prototype probes. The design of the other prototype probes was kept very similar, where the dimensions of the speaker seat in the body part is adjusted and the cap is changed to fit accordingly. The body also forms the acoustic channel that connects the ear canal to the sound port of the speaker. The wall thickness of the probe tip is $0.3\,\mathrm{mm}$. The probe tip dimension was kept the same for all our prototype probes to allow for easier comparison. Finally, to close the gap between the probe tip and the ear canal, commercially available ear tips were used, which can be slid on. The backsides of our prototype

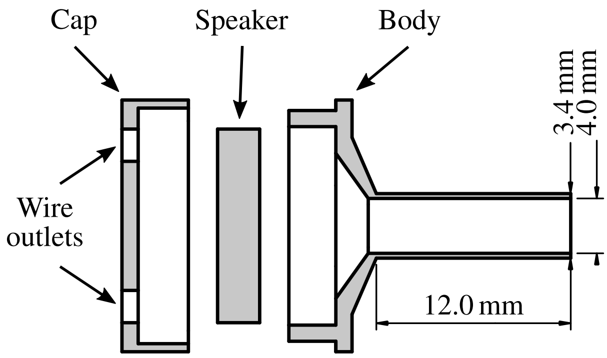


Figure 5.4: Exploded-view drawing of the *Soberton RC-1206S* prototype probe.

probes were closed off with a cap, which had the required holes to feed the wires through that lead to the speaker. The cap and the wires were glued in place during assembly to create an airtight seal in the probe itself. The finished prototype probes can be seen in Figure 5.3.

5.5 Probe Characterization

To evaluate the performance of our prototype probes, they were acoustically characterized. Their behavior when driven as speakers and recorded from as microphones were measured in independent experiments. All measurements were done with an *National Instruments PXI-4461* sound card. Reference for all measurements of acoustic properties is a *Larson Davis 824* sound level meter (SLM) system [164], including a *2540* free field microphone, a *AEC 304* occluded ear simulator and a *CAL 200* $94\,\mathrm{dB\,SPL}$ at $1\,\mathrm{kHz}$ calibrator.

5.5.1 Speaker Response

The frequency response of our prototype probes, while driving the speaker, was measured in an *AEC 304* ear simulator. This ear simulator replicates the acoustical properties of an ear canal of a human adult. The sound pressure measured by the built-in microphone corresponds to the sound pressure at the ear drum. Therefore, we measure which electric level at the speaker results in which sound pressure level at the ear drum. However, for each ear canal and each time the probe is inserted, the acoustic properties change slightly. An ear simulator offers high repeatability of measurements, but the results can usually not be generalized directly. During an OAE screening measurement, a specific sound pressure at the ear drum is needed within a certain margin. This means in practice that the level of the stimulus has to be adjusted for each insertion into an ear canal by doing an in-ear calibration.

In this experiment, a linear chirp is used to measure the frequency response. The level of the stimulus is adjusted for each prototype probe so that the sound pressure is roughly the same in all measurements. The stimulus is given as electrical voltage to the speaker of the prototype probe. The immediate response is the electrical voltage recorded from the ear drum microphone of the ear simulator. All calculations are done in frequency domain and only the magnitude is considered. The sensitivity function of the prototype probes in Pa/V can now be calculated as

$$S_{Speaker} = S_{EarSimulator} \times \frac{U_{Response}}{U_{Stimulus}}.$$

$S_{EarSimulator}$ is the sensitivity of the ear simulator, assumed flat and is calibrated at $94\,\mathrm{dB\,SPL}$ at $1\,\mathrm{kHz}$ with the *CAL 200* in units of Pa/V. $U_{Stimulus}$ is the frequency response of the linear chirp stimulus used. $U_{Response}$ is the frequency response of the signal recorded by the ear simulator. Finally, $S_{Speaker}$ is the resulting sensitivity function of the prototype probe tested. The chirp can be repeated multiple times to lower noise in less sensitive frequency regions by averaging recordings.

Figure 5.6(a) shows the results of this measurement for each prototype probe. The click stimulus during a TEOAE measurement should ideally activate the full spectrum equally at all frequencies. Consequently, a flat frequency response would be best. However, since TEOAEs are most effective on frequencies below $5\,\mathrm{kHz}$, an attenuation at higher frequencies is acceptable. At low frequencies, a high attenuation will result in insufficient stimulation and the OAE response will not be measurable. Thus, the results already show problems with the *CUI CDM-10008* and *Soberton RC-1206S* prototype probes. Finally, an absolute shift in sensitivity can easily be compensated by adjusting the level of the stimulus.

5.5.2 Settling Behavior

The click stimulus in a TEOAE measurement has a duration of typically $100\,\mu\mathrm{s}$. A few milliseconds after, the TEOAE will arrive at the probe. At this point in time, if the speaker membrane is still resonating from emitting the stimulus, it will disturb the measurement. This effect is also referred to as “ringing” and may also occur in conventional TEOAE probes, where the settling oscillation of the speaker membrane can be measured in the ear canal. In this measurement, we compare the settling behavior of our prototype probes to each other using the *AEC 304* ear simulator. The probe under test is set up to emit a pulse of $100\,\mu\mathrm{s}$ duration. The output amplitude is adjusted such that a level of $80\,\mathrm{dB\,peSPL}$ can be measured at the ear simulator microphone [100]. These settings are similar to actual TEOAE measurements.

To compare the prototype probes to each other, the root mean square (RMS) value of the measured signal at the ear simulator microphone in the window of $4\,\mathrm{ms}$ to $8\,\mathrm{ms}$ after the click is calculated. Table 5.1 shows the results, listing the required output (stimulus) level and the measured settling RMS value. The *PUI SMS-1508MS-2-R* probe shows excessive activity of almost $1\,\mathrm{mV}$ and the *CUI CDM-10008* probe has a similar behavior. The other probes perform well enough as a certain settling activity can be compensated by the non-linear pulse protocol used during TEOAE recording. Additionally, the output level required for each prototype probe to achieve the given sound pressure level corresponds to the findings in the previous broadband measurement.

5.5.3 Recording Response

All measurements so far have only evaluated the stimulating (speaker mode) performance of our probes. To accurately evaluate the recording properties, the prototype probes need to be excited by an external source. In a standard OAE probe, one can connect it to an ear simulator and use the built-in speaker of the probe to generate the stimulus. This usually works well with low frequencies. However, at higher frequencies ($3\,\mathrm{kHz}$ to $5\,\mathrm{kHz}$), standing waves in the cavity will lead to variation in the sound pressure. This leads to different sound pressures at the ear-drum microphone of the ear simulator and the probe microphone. Consequently, this is also an issue when doing the in-ear calibration before an actual OAE measurement.

One possible calibration setup for OAE probes was proposed by Siegel [152] and refined by Rasetshwane et al. [141], of which a more detailed description is given in Section 2.4.3. Here, a hard walled tube ($8\,\mathrm{mm}$ syringe) is used to form a cavity, representing the ear canal. On one opening, a sound source is inserted. On the other opening, a tube microphone is radially inserted. This leaves the second side open to insert a reference microphone from a calibrated SLM. After the first step of calibration, the SLM is removed and the probe to be tested is inserted. For accurate results, the tube microphone needs to be on the same plane in the cavity as the SLM or the probe under test. Also, exact placement and repeatable insertions are necessary for reproducible measurements.

To achieve that, a custom calibrator was designed and manufactured using the same SLA 3D printer as for the probes. The resulting device can be seen in Figure 5.5. The sound source is realized with a *CUI CDM-10008* speaker and the radially mounted tube microphone is a *Knowles EM-23346-C36*. The opening on the right fits a standard ½ inch microphone and is sealed by an o-ring. When an OAE probe is inserted, an appropriate probe tip has to be used.

The speaker of the calibrator is used to generate a broadband signal. We used a linear chirp with constant amplitude. Other broadband signals may also be used, especially, if one wants to emphasize certain frequency regions. The used stimulus will later cancel out. However, uniform excitation is necessary for good results. If the resulting recordings are noisy, the measurements may be repeated several times and averaged in time domain to lower the noise floor.

The procedure for calibrating OAE probes consists of two steps. First, a calibrated SLM microphone is inserted. The sound pressure in the cavity is recorded by the tube microphone and the calibrated SLM microphone (reference microphone). The transfer function between the reference microphone and the tube microphone is:

$$H_{ref/tube\,1} = \frac{U_{ref}}{U_{tube\,1}}$$

Where U_{ref} and U_{tube1} are the frequency transformed recordings and $H_{ref/tube1}$ is the resulting transfer function. In the second step, the reference microphone is removed and the process is repeated with the probe under test inserted. The transfer function is accordingly:

$$H_{probe/tube\,2} = \frac{U_{probe}}{U_{tube\,2}}$$

To get the sensitivity function of the probe under test S_{probe}, one has to calculate the transfer function from the reference microphone to the probe and multiply that by the sensitivity of the reference microphone S_{ref}:

$$S_{probe} = H_{probe/ref} \times S_{ref} = \frac{H_{probe/tube\,2}}{H_{ref/tube\,1}} \times S_{ref}$$

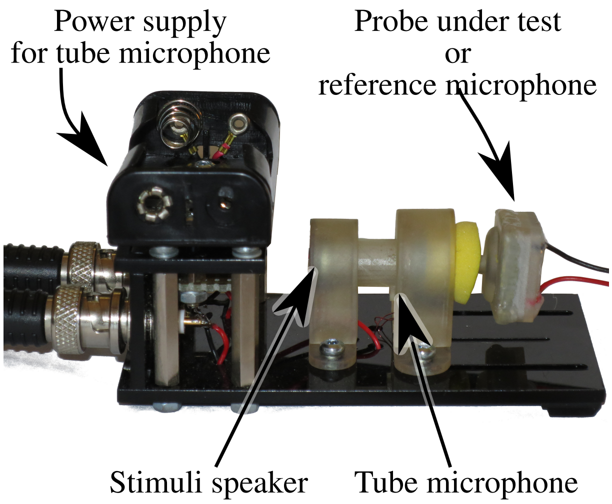


Figure 5.5: Custom calibrator for OAE probes.

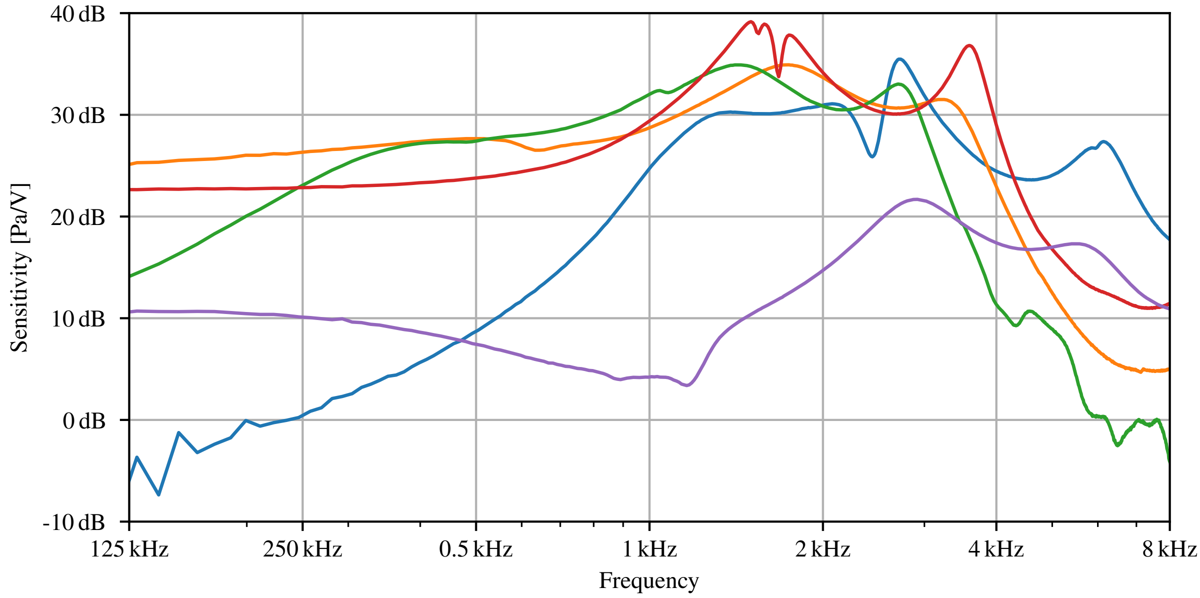
The sensitivity function of the reference microphone is flat in our SLM and the offset is measured in $\mathrm{Pa/V}$ with a $1\,\mathrm{kHz}$ acoustic calibrator.

The results can be seen in Figure 5.6(b). In our case, we recorded from our prototype probes with an additional $40\,\mathrm{dB}$ amplifier on the input of the sound card to sufficiently raise the signal levels from the noise floor. This gain was subtracted before plotting.

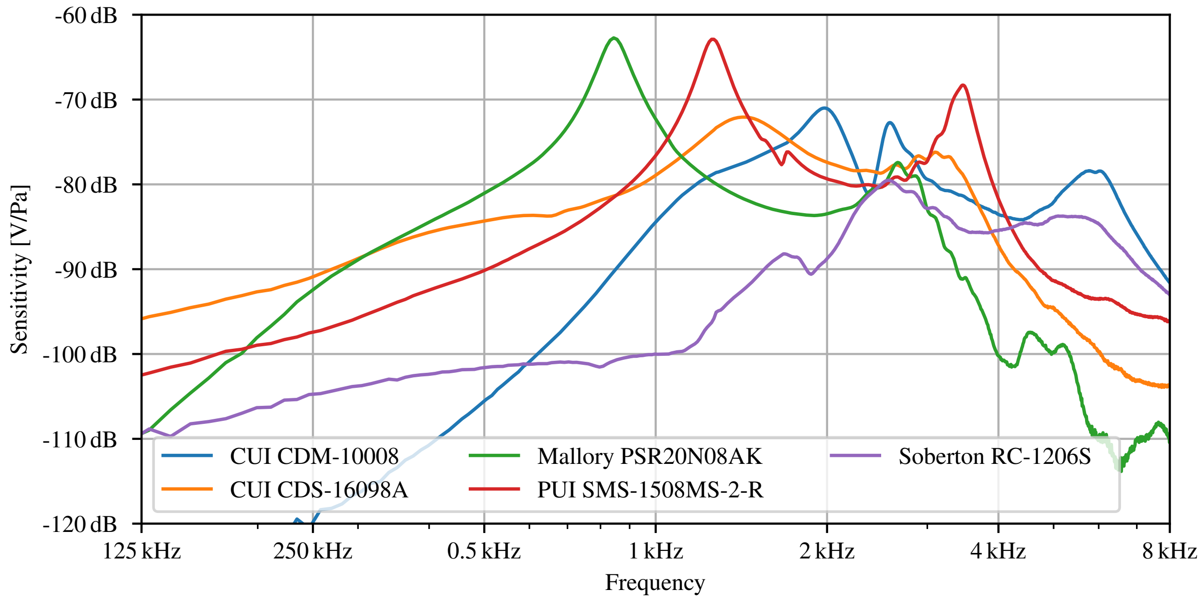
Similar to the speaker response, a flat frequency response during recording is desired. Besides the used speaker in the probe, most of the acoustic behavior is governed by the mechanical properties of the probe body. Therefore, many features will be visible independent of whether a speaker is used to emit or record sound. Of the evaluated prototype probes, the *CUI CDS-16098A* performs best. In the most important frequency regions for TEOAE, the sensitivity is adequate, however, it declines fast above $4\,\mathrm{kHz}$. For reference, an electret microphone-based probe would have a sensitivity of about $-30\,\mathrm{V/Pa}$. Finally, to cross-check the findings of this measurement, all prototypes probes were measured in a fixed frequency acoustical calibrator (*Larson Davis CAL200*). It emits a sine of $94\,\mathrm{dB\,SPL}$ $(1\,\mathrm{Pa})$ at $1\,\mathrm{kHz}$. The results can be seen in Table 5.1 and match the measurements in our custom calibrator.

5.6 Measurement Setup

The probe characterization measurements show that measuring TEOAEs with our simplified probe design is possible. To verify this we implemented a measurement system using the same sound card as was used for the previous measurements. Unlike the previous measurements, where the speaker was either driven or recorded from, we now need to do both simultaneously. So the main challenges are the overall low sensitivity when recording and the concurrency of input and output. With the results of the prototype probe characterization in mind, we will go forward and design our system around the *CUI CDS-16098A* and *Mallory PSR20N08AK* prototype probes.



(a) Speaker sensitivity measured in ear simulator.



(b) Recording sensitivity measured in a custom calibrator.

Figure 5.6: Sensitivity of the single speaker-based prototype probes when driven as speakers and recorded from in microphone mode.

Table 5.1: Summary of the properties of the prototype probes.

Speaker	Impedance	Pulse amplitude for $80\,\mathrm{dB\,peSPL}$	Settling RMS	Sensitivity at $1\,\mathrm{kHz}$
	Ω	mV	$\mathrm{dB\,V}$	$\mathrm{dB\,V/Pa}$
CUI CDM-10008	8	12.6	-70	-86
CUI CDS-16098A	8	10.2	-84	-80
Mallory PSR20N08AK	8	11.5	-79	-67
PUI SMS-1508MS-2-R	8	8.2	-62	-78
Soberton RC-1206S	32	39.8	-88	-101

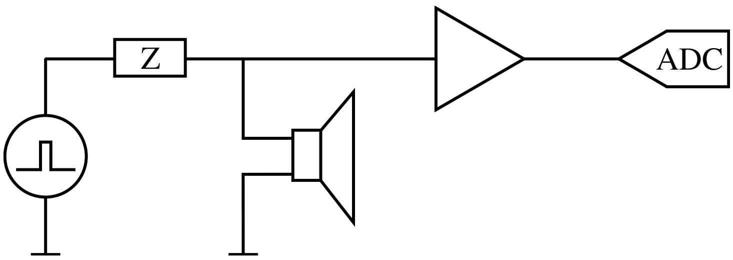


Figure 5.7: Schematic of the measurement setup.

5.6.1 Hardware

Figure 5.6(b) shows a sensitivity of about $-75\,\mathrm{dB\,V/Pa}$ for our prototype probes in the relevant frequency regions. We want to detect TEOAEs, which have sound pressures of about $-5\,\mathrm{dB\,SPL}$ to $20\,\mathrm{dB\,SPL}$. Assuming a sound pressure of $-10\,\mathrm{dB\,SPL}$, which is $-84\,\mathrm{dB\,Pa}$, we can expect a signal strength of about $-159\,\mathrm{dB\,V}$. The used *NI PXI-4461* sound card has an idle noise of $-115\,\mathrm{dBV_{rms}}$ at the optimal settings. Thus, the signal strength has to be raised, without increasing the noise level at the same rate. We chose to built a $50\,\mathrm{dB}$ amplifier based on the *Analog Semiconductor SSM2019*. This integrated circuit (IC) is a self-contained audio preamplifier with very low noise.

The signal levels for the click generation (stimulus) are easier to handle. An analog output of the sound card was used. However, the output is low impedance and cannot be switched to high impedance during a measurement. If the input and output would be connected in parallel to the prototype probe speaker, the recorded signal strength would decrease even more. To remedy this, we chose to increase the impedance of the analog output with a series resistor. The dynamic range is sufficient to drive the speaker, however, higher drive amplitudes of the analog output come with higher noise levels. An impedance of $1\,\mathrm{k\Omega}$ was chosen as compromise between reduced signal level and introduced noise. Figure 5.7 shows the circuit, with the analog output of the sound card as click source on the left and the analog input on the right.

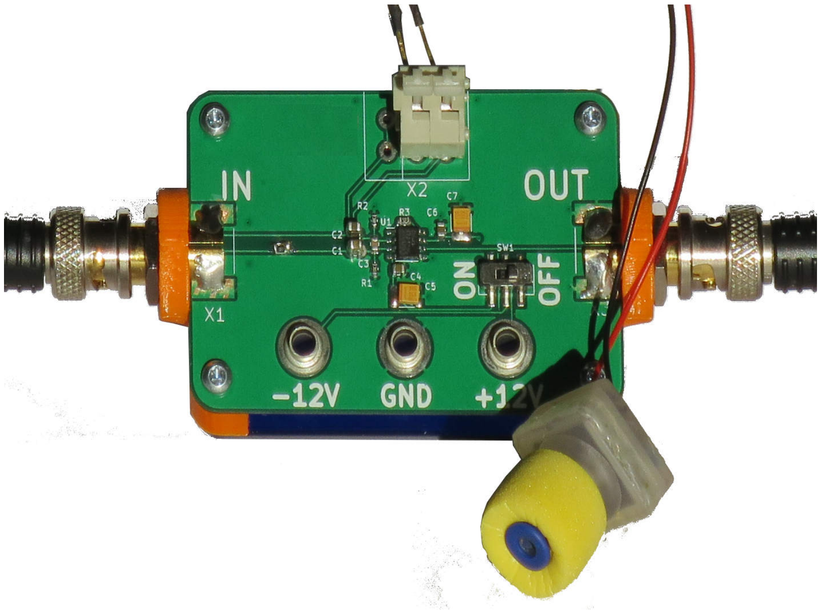


Figure 5.8: Photograph of the measurement setup with the custom printed circuit board (PCB).

To reduce the number of connections, reduce noise and increase reliability of our measurements, the electronic circuit was implemented on a custom PCB. Figure 5.8 shows the resulting device. The amplifier is powered by an external battery to further reduce noise. The prototype probes can be directly connected to the device with short leads using a spring clamp terminal block. The incoming stimulus signal as well as the amplified output signal are connected to the sound card with BNC connectors. The performance of the amplifier setup was verified similar to the prototype probes, with a linear chirp and different impedance resistors. The device was found to be linear and flat in frequency response.

For all following recordings, besides the anti-alias filter of the sound card, a digital filter was used. This finite impulse response (FIR) band pass filter was configured to block frequencies below $500\,\mathrm{Hz}$ and above $5\,\mathrm{kHz}$.

5.6.2 Recording evaluation

During the measurement of TEOAEs we need to separate the linear from the non-linear components of the recordings: After a click is emitted into the ear canal, one can observe multiple reflections in the recordings, for example the reflections inside the ear canal from the ear drum. These linear reflections typically drown out the much weaker OAEs. However, the OAEs originate from a non-linear process in the inner ear. Therefore, a specific pulse pattern can be used to separate linear reflections from the non-linear OAEs. In our following measurements, we used the protocol described by Kempt et al. [83]. In this protocol, three clicks of equal amplitude are emitted and the responses are recorded for each click. A fourth click with inverted polarity and three times the amplitude is emitted afterwards. By averaging all four responses of this click sequence, the linear components can be eliminated and the TEOAE response remains. The click has a duration of $100\,\mu s$ and the recording window after each click lasts typically $20\,\mathrm{ms}$. The duration of one click sequence is therefore $80\,\mathrm{ms}$.

Since the TEOAE signal is so minuscule, a single recording of one click sequence is usually not sufficient to determine the presence of an OAE. The noise floor in the recording is lowered by averaging multiple click sequences. Usually, the measurement is continued until a timeout is reached or an OAE is found in the recording.

To distinguish between the signal and the noise in the recording, the click sequences are summed and averaged in two independent buffers a and b. Or put differently: The first and all other odd numbered click sequences are averaged into buffer a and even numbered click sequences are averaged into buffer b. These buffers can now be compared to each other. The evaluation window in our measurements is $5\,\mathrm{ms}$ to $13\,\mathrm{ms}$. The signal component is defined as the sum of both buffers and calculating the RMS value in this window:

$$Signal = RMS\left(\frac{a+b}{2}\right)$$

Whereas the noise value is the difference of both buffers and again calculating the RMS value:

$$Noise = RMS\left(\frac{a-b}{2}\right)$$

Expressing both calculated values in dB allows for an easy comparison. The difference of both logarithmic values is the signal to noise ratio (SNR). The SNR represents the relative level of the OAEs in our recording, thus eliminating the need for absolute calibration of our measurement system in terms of sound pressure level (SPL). An SNR of $6\,\mathrm{dB}$ is considered sufficient for the presence of an OAE.

Another criterion is the correlation between the a and b buffer. If it is high, both buffers are very similar to each other and the measurement is considered stable.

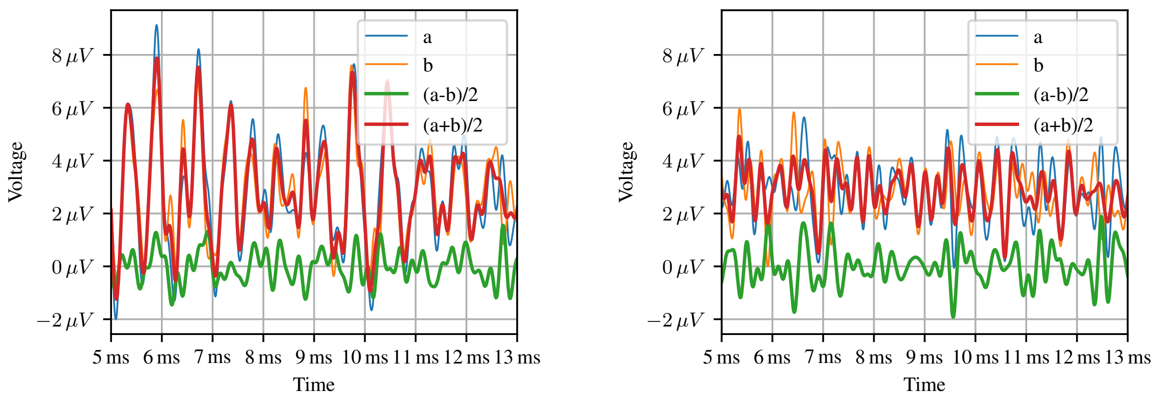
5.7 Experimental Results

To verify that the proposed probe design can measure TEOAEs, a small study was conducted. The measurements were done on four normal hearing adults (one measurement per ear) with the two selected probes, *CUI CDS-16098A* and *Mallory PSR20N08AK*. Normal hearing was established by measuring each ear with a commercial OAE screening device. The measurements were executed with a fixed length of 1000 click sequences each rather than stopping when a SNR threshold is reached. One subject could not be measured with the *Mallory PSR20N08AK* probe due to its size in the auricle. Table 5.2 shows the results. The recordings of the marked rows (†) can be seen in Figure 5.9. Figure 5.9(a) shows an example recording with an OAE response present. In this particular measurement, the recording reached a SNR of $6\,\mathrm{dB}$ after 400 pulses. So the measurement would have taken $23\,\mathrm{s}$ if it was stopped after reaching the threshold.

Of 14 measurements in ears with externally established normal hearing, our measurements resulted in a “pass” ($SNR \geq 6\,\mathrm{dB}$) in 10 cases and “refer” in four after the full measurement

Table 5.2: Experimental results data overview.

DUT	Signal dBV	Noise dBV	SNR dB	Correlation
CUI CDS-16098A	-113	-123	†10	0.83
	-115	-122	7	0.66
	-116	-121	5	0.51
	-111	-118	7	0.69
	-111	-119	8	0.70
	-111	-119	8	0.73
	-108	-120	12	0.90
	-109	-122	13	0.90
Mallory PSR20N08AK	-117	-121	4	0.41
	-117	-121	4	0.44
	-112	-119	7	0.70
	-113	-118	5	0.59
	-110	-119	9	0.76
	-108	-121	13	0.91
Ear simulator AEC304				
CUI CDS-16098A	-120	-121	†1	0.18
Mallory PSR20N08AK	-121	-121	-1	-0.08



(a) TEOAE present with 10 dB SNR.

(b) TEOAE absent in passive ear simulator.

Figure 5.9: Example TEOAE recording with the single speaker-based probe.

time. The required criterion could have been reached with more averages. However, if a normal TEOAE probe would have been used, these measurements would have take mere seconds.

To verify that we would not detect a signal when no OAE is present, each prototype probe was tested in the *AEC 304* ear simulator, with the same settings. Figure 5.9(b) shows the resulting recording. The low SNR and correlation values indicate the correct behavior of our prototype probes and measurements.

5.8 Chapter Summary

In this chapter, we proposed a novel simplified TEOAE probe, which only needs one transducer instead of two. We designed and assembled five prototype probes, based around different commercially available speakers. All probes were characterized with standard measurement equipment and our custom built probe calibrator. Two of the selected probes were used to show the feasibility of our idea in an actual OAE measurement.

However, these results should only be considered as the foundation for developing a full prototype ready for manufacturing. Based on these existing early prototypes, further optimizations can be done. Especially systematic improvement of the acoustical characteristics are necessary, which are largely dependent on the mechanical properties.

For these measurements, we used high quality measurement equipment. However, we intent to follow up with a cost effective solution for adapting the signal to either a smartphone or a standalone solution.

Another prospect would be the usage of in-ear headphones. They are set up almost exactly the same as our probes. However, so far we found their acoustic characteristics lacking for this application. We expect high benefits of this route since in-ear headphones are readily available at a very low cost.

6
Concluding Remarks

In this thesis, multiple solutions towards mass-deployable OAE-based hearing screening were introduced, evaluated and discussed. All three approaches aim to lower the overall cost of manufacture and usage, as well as to improve the usability by laypersons. Further, the goal was to improve measurement results under adverse measurement conditions. Each approach offers its individual potentials and further challenges.

This concluding chapter of this thesis is structures as follows: First, the solutions presented in the three preceding chapters are compared to each other as well as to typical commercially available systems. Next, three possible usage scenarios for mass-deployable OAE-based hearing screening are discussed, for which the potential use cases of the solutions presented in this thesis are highlighted. At the end of this chapter, a concluding summary of this thesis is given and potentials for future research discussed.

6.1 Comparison of Hearing Screening Solutions

In each of the three previous chapters, different approaches to mass-deployable objective hearing screening were discussed. Each chapter followed different strategies and aspects of low-cost and easy to use OAE-based hearing screening. As a result, the presented solutions offer distinct capabilities. In this section, the proposed approaches are compared to each other. Further, it is discussed, how these approaches compare to existing and established OAE-based hearing screening systems.

A measurement system for OAEs can be divided into the ear-probe and the measurement device, which connects to the ear probe. The low-cost standalone device introduced in Chapter 3 as well as the smartphone-based approach in Chapter 4 discuss novel concepts, which are mostly aimed towards the "measurement device" side of the system. This is in contrast to the single speaker-based probe of Chapter 5, which is focused on the ear probe. Table 6.1 gives an overview of the features of each approach in qualitative comparison to existing off-the-shelf OAE-based hearing screening solutions. This comparison is discussed next.

Table 6.1: Qualitative comparison of the presented low-cost hearing screening solutions in this work, compared to commercially available OAE-based hearing screening systems.

		Low-cost Standalone Chapter 3	Smartphone-based Chapter 4	Single Speaker-based Chapter 5
Hearing screening	OAE protocol	TE-/DPOAE	TE-/DPOAE	TEOAE
	Preparation time	+	○	(+)
	Measurement time	○	○	– –
	Robust to blockage	○	○	++
	Cleaning/hygiene	○	○	+
Manufacturing	No. of parts	+	+	+
	Complexity	+	+	++
	Reliability	+	○	○
	Cost (OOM)	100 €	100 €	1 €
	Single use possible	✗	✗	✓
HMI and usability	Intuitive usage	+	+	○
	User guidance	○	+	n/a
	Error guidance	limited	comprehensive	n/a
	Patient data entry	–	++	n/a
Integration	with CDMS	○	+	n/a
	with telemedicine	○	++	n/a

(+: improve, ○: similar, –: regress, n/a: not applicable)

Hearing Screening Capabilities

A central strategy, which is common to all discussed solutions in this thesis, is the support of standard OAE measurement protocols. TEOAE and DPOAE are commonly used for hearing screening. Both of these OAE measurement protocols are very well understood and researched. Thus, setting up a hearing screening program, even for personal use, benefits from the use of these standardized protocols. Additionally, by using the established protocols, screening results are more meaningful when compared between devices of different manufacturers.

While all solutions discussed in this thesis are based on the excitation and measurement of TEOAEs and DPOAEs, the measurement procedure, which also includes the preparation of the measurement, can differ from that of typical hearing screening systems. The preparation includes connecting the ear probe to the measurement device, fitting the ear tip to the ear probe, as well as placing the ear probe into the patients ear and starting the actual measurement. The ear tip is a consumable that must be replaced between each patient. After the measurement, the ear tip must be removed from the ear probe and disposed. Additionally, the ear probe needs to be cleaned or disinfected after usage. When using the standalone device, where the ear probe is merged into the device body, no additional setup time is required for ear probe handling, except for fitting the ear tip. With the insertion of the ear probe into the patient's ear, the measurement can immediately begin. This insertion can be detected by the standalone device, and the measurement starts automatically once the acoustic behavior is plausible. When using a conventional measurement system, the ear probe fit in the patients ear needs to be tight enough, such that the probe will not fall out of the ear canal from its own weight or the weight of the cable. With the standalone device, which is held by the examiner during the measurement, this is not a requirement. The preparation time of a measurement system using a single speaker-based probe can also be reduced, if the per unit cost is so low that the ear probe itself is a consumable. In that case, the ear probe could be pre-equipped with the soft ear tips, which can then be molded directly on the ear probe tip. This would eliminate the otherwise necessary steps of fitting the ear tip to the ear probe, as well as cleanup after use. However, this "wasteful" strategy might lead to unintended reuse of consumables, especially in a low-resource context.

While the preparation time can be lowered when using the single speaker-based probe, the measurement time increases significantly, compared to measurement systems using conventional OAE ear probes. This is mostly due to the extremely low sensitivity of a speaker, when used as a microphone, which requires the use of a high-gain amplifier. This configuration will always result in a noise level after amplification that is inferior to dedicated microphones and, hence, in a longer measurement time as the noise levels during measurement are the determining factor. In contrast, the dedicated standalone device and the smartphone-based system performed comparable to existing systems. However, for the smartphone-based system, this is limited to certain selected and approved smartphones since a significant share of available smartphones is entirely or partly unsuitable for the measurement of OAEs.

An advantage of the novel probe architecture of the single speaker-based probe is the layout of the acoustic channels in the ear probe tip. In a conventional ear probe, each transducer (microphone/speakers) needs a separate acoustic channel into the ear probe tip, which has typically a diameter of just a few millimeter. This results in even smaller diameters of each acoustic channel. In the single speaker-based probe, the full ear probe tip can be utilized by a single acoustic channel, which can use the full diameter. This makes the single speaker-based probe design much less prone to blockage and even cleaning the acoustic channel can be achieved without a specialized procedure.

Manufacturing

One key aspect of this thesis is the cost reduction of objective hearing screening solutions. This is, among others, achieved by utilizing existing platforms, e.g. smartphones. Another approach is the usage of low-cost high quality audio components, which became available due to the proliferation of smartphones and other consumer electronics. This has led to the availability of extremely well suited electronic components like audio codecs, as well as acoustic transducers, i.e. microphones and speakers. All solutions in this thesis utilize these components. However, while the per unit manufacturing cost is lowered by using these parts, the major contribution to per device cost is expected from the simplification of the manufacturing process and the novel architectures.

The low-cost standalone device, where the ear probe is merged into a probe body, does not need a dedicated probe cable. This simplifies the assembly of the ear probe as well as the device, which often requires manual soldering of the individual wires. This process, involving the subminiature transducers in the ear probe, is error prone and requires experienced workers. By merging both subsystems, device and probe, it is possible to design a probe which solely relies on electrical connections provided by a PCB, which can be assembled automatically with standardized machinery. This lower part count and complexity does not only lead to a lower per unit cost, but also improves the reliability by removing critical points of failure.

The manufacturing complexity of the smartphone-based approach lies mostly in the smartphone itself. Since smartphones are a high volume commodity product, their component sourcing, manufacturing and distribution is extremely optimized, leading to low per unit costs and constant quality. By outsourcing the majority of the complexity of a hearing screening system into a smartphone, its optimized manufacturing process can be utilized. With the strategy presented, only a minimum of additional components is needed, i.e. the ear probe. As discussed, not every smartphone is suitable for OAE-based hearing screening, which makes it impractical for examiners to use their own device. A more sensible choice is to provide a smartphone together with an ear probe in a bundle. Compared to the low-cost standalone device, this approach only needs to manufacture and provide the dedicated ear probe, while most parts remain an off the shelf commodity, which do not need any application specific modification.

The single speaker-based ear probe architecture has the most substantial impact on manufacturing of all presented solutions. The buildup of the probe only consists of a single electrical transducer and a minimum of mechanical parts that form the ear probe body. Since only a single transducer must be placed inside the ear probe body, a larger lower-cost transducer can be chosen. This makes assembly of the probe simpler and less error prone, since only two wires need to be connected to a larger size transducer. In a commonly available TEOAE ear probe, at least five wires need to be connected to miniature transducers. The basic structure of the single speaker-based ear probe is identical to that of in-ear earphones: A speaker is connected to the ear canal, which is sealed off with a soft silicone rubber tip. If it succeeds to directly use in-ear earphones for OAE hearing screening, the cost per ear probe could be as low as 1 €. For in-ear headphone-based probes, the existing production facilities can be used. However, using this probe architecture requires slightly more complex electronic circuitry to drive the speaker and record from it at the same time. Due to the expected high cost reduction, it would be feasible to provide this probe as a single-use item, which would eliminate the cost for cleaning in-between patients and maintenance, e.g. calibration.

All three approaches presented in this thesis offer a high potential for cost reduction during manufacturing. By utilizing standardized and established manufacturing processes, the fixed cost for setting up the production can be lowered. The variable costs are lowered by using fewer lower-cost components and eliminating labor intensive manual assembly steps.

HMI and Usability

The per unit cost of objective hearing screening systems is only one aspect in improving the global coverage of hearing screening. Another is the usability of such hearing screening systems by untrained personnel. In many areas, especially in rural areas of low and middle-income countries, hearing screening needs to be performed by persons without audiological or sometimes even without any medical background at all. For example, those persons can be midwifes who perform hearing screening after home births or school teachers that screen entire classes.

The low-cost standalone device, with its cable-free setup, can be almost as simple to use as an in-ear infrared fever thermometer. After attaching the appropriate probe tip, the measurement can immediately begin. Since the low-cost standalone hearing screening device must be held by the examiner during the actual OAE measurement, the seal of the ear canal must not be as tight as with a typical OAE ear probe, where the seal must be strong enough to hold the probe in the ear canal without falling out. However, due to the small form factor, the human machine interface (HMI), consisting of a display and buttons, must be kept minimal. This limits the amount of meaningful interaction between the device and the examiner. On one hand, the ordinary workflow of an OAE hearing screening measurement does not require intensive interaction. In this case, the measurement needs to be started with a single button press and will show the results after completion. The result is either “pass” or “refer”. On the other hand, the measurement can also fail and yield an inconclusive result due to a number of reasons, some of which can only be rectified by an experienced examiner. For the untrained examiner, however, the device cannot directly offer extensive guidance in such cases due to the limited HMI. For error guidance, an external manual or a connected smartphone would be needed. Both require additional steps by the examiner. Finally, such a low-cost standalone device could also be equipped with additional sensors. The resulting data can then be used for an improved feedback to the examiner.

The smartphone-based approach, in contrast, offers comprehensive possibilities in terms of user interaction. The user interaction of smartphones is fundamentally designed for intuitive use. Basic usage of smartphones can be learned almost without guidance or even training. Additionally, due to the ubiquity of smartphones, even in low and middle-income countries, most people are already familiar with them. As such, a smartphone-based objective hearing screening solution would build on these established user interfaces. In addition, smartphones are universally equipped with large high resolution displays. These, together with the touch interface, can be used for comprehensive guidance through the complete process of OAE hearing screening, from probe preparation, through actual measurement to interpretation of the results.

Overall, improvement of usability for untrained users highly depends on a suitable user interface. This is especially important if problems occur during the measurement, which must be rectified by the examiner, for example by readjusting the probe in the ear canal. In summary, integrating a smartphone in any hearing screening solution can lower the barrier for untrained users.

Integration and Connectivity

Another capability of smartphones, besides the user interface, is the high connectivity. Smartphones can connect to network services either by connecting to Wi-Fi or a broadband network. In a clinical setting, this feature can be used to connect to a local clinical data management system (CDMS) to store diagnostic results for each patient. In a hearing screening context, it can prove especially helpful for follow-up audiologic evaluations. If a screening measurement does not yield a “pass”, this can either be attributed to adverse measurement conditions or actual hearing loss. In any case, a follow-up audiologic evaluation, and possibly treatment, is necessary. However, some patients get lost on follow-up for various reasons. A major reason is that hearing screening is regularly conducted in situations or facilities that do not involve an audiologist or ear, nose, and throat (ENT) specialist. In these cases, a “refer” implies visiting a specialist, possibly in another city. The use of a CDMS might help to keep track of such cases and increase the follow-up rate. A common commercial OAE hearing screening system is capable to store patient data and measurement results on the device itself. The data can then be synchronized with either a personal computer (PC) or a smartphone as gateway. A similar indirect workflow must be used with the presented low-cost standalone device, as it only has local connectivity. However, a smartphone-based hearing screening system can connect directly to CDMS services without additional steps.

Finally, a smartphone-based hearing screening solution offers the potential for excellent integration with telemedicine. It would be possible to connect with an expert audiologist during an OAE measurement, e.g. via a video call. This audiologist could then guide through the complete measurement and discuss the results and necessary follow-up steps. Another possibility would be that the remote audiologist is connected in the case of problems during the measurement or for interactive training, without the need for the user to go somewhere. This integration of telemedicine, however, is only possible with an approach that includes a smartphone. For the presented low-cost standalone device, an additional smartphone would be needed, at least during the telemedicine sessions.

Summary

The presented approaches and architectures in this thesis successfully lower the manufacturing cost and complexity, compared to common commercially available OAE based hearing screening systems. Additionally, they offer the potential for lowering the barrier for administering objective hearing screening tests by untrained personnel. At the same time, screening quality can be kept the same by relying on the well known TEOAE and DPOAE measurement protocols. This makes the measurement results of the presented approaches comparable to other measurement systems. In the following section, it is discussed how the presented approaches can be used in a number of usage scenarios and how to fully utilize the individual capabilities.

6.2 Usage Scenarios

The benefits of hearing screening and early detection of hearing loss have been acknowledged. If hearing loss can be detected early, the outcomes of rehabilitation measures and individual cognition generally improve. This is, among other things, reflected in the implementation of universal neonatal hearing screening (UNHS) programs around the world. Besides the application in UNHS, the approaches presented in this thesis can also be applied in other settings, where the overall expenditure for comprehensive hearing screening can be lowered, if the hearing screening tests could be administered by a layperson and not by a medical professional.

The remainder of this section introduces three potential usage scenarios, where the mass-deployable objective hearing screening techniques presented in this thesis can be used. While some of these techniques may also be incorporated into screening devices for regular clinical use, these scenarios focus on settings, where coverage of hearing screening is currently lacking due to limited funds and insufficient medical personnel, especially in low and middle-income countries (LMICs).

UNHS in low and middle-income countries
The implementation of UNHS programs has advanced in recent years, however, the global coverage is still far from complete. Only $33\,\%$ of the worlds population lives in areas, where the coverage of UNHS is above $85\,\%$ [124], whereas another third of the population has virtually no access to functioning UNHS. In those countries, the gross domestic product (GDP) per capita is approximately 10 times lower compared to countries with complete coverage.

Additionally, a major problem for those living in rural areas is the distance needed to travel to receive appropriate health care. This might be due to unavailable means of transport, cost of transport or distance. Strategies to improve hearing screening coverage for rural populations are screening camps [20], screening at home [132], screening by primary health care providers [48] or screening during vaccination [48]. In these low-resource settings, the health care providers are usually general practitioners or nurses, without profound specialized training in hearing care. In these situations, hearing screening could also be only a subordinate part of the other health care activities.

As a result, it is exceedingly important that the hearing screening system can be used with minimal training, that the screening can be performed quickly, and that the system is low-cost and can withstand harsh operational conditions outside of a clinic. These requirements make the hearing screening system presented in Chapter 3 highly suitable. The compact low-cost standalone device is highly portable and can easily be carried alongside other medical equipment that is also often used in general practice. These already include medical devices such as otoscopes, blood pressure monitors, medical thermometers or pulse oximeters, some of which are also used for examination and screening of newborns and small children. One of the central advantages of the low-cost standalone device is that it can be used quickly, without much preparation or setup, by only attaching a new ear-tip before each patient. Finally, this system could also be equipped with additional hardware to be able to perform measurements in noisy environments as described in Section 2.4.6.

In the scenario described here, hearing screening will be accompanied by a health care professional, even if not by a specialist in hearing care. If the screening results in a “refer”, the health care professional can then provide the necessary information. These must include explanations and guidance of the parents regarding the meaning of the results as well as to highlight the importance of the follow-up examinations. If the health care providers are local to the community, e.g. a primary health care provider, they can also check up on patients referred, to encourage them to seek further specialized health care in time.

Institutional Hearing Screening

Institutional hearing screening includes organized screenings at schools, public institutions, factories and similar. These screening situations have in common that a larger group of people is screened directly at the respective facility. These are school-based programs [185] or hearing screening aimed at adults with an increased risk due to noise exposure, such as traffic patrol officers or factory workers. These screenings are usually conducted by a trained medical professional. However, to increase coverage and lower barriers of access to hearing screening, it would be of great benefit if the screening was performed by a layperson. In this situation, an easy to use hearing screening system is of great importance.

In this scenario, the smartphone-based hearing screening solution presented in Chapter 4 is the most suitable solution. The benefits and usefulness of using smartphones for hearing screening such as intuitive user interface and high connectivity has already been acknowledged in the past [21]. However, all existing solutions are based on subjective tests. Our objective OAE hearing screening system could be a useful addition to complement the existing screening methods. It could be used for the integration of telemedicine, either to assist with the screening, or for a first level of medical consultancy in the case of a “refer”.

A smartphone-based screening system is not limited to either subjective hearings tests or objective OAE-based tests. With the approach presented in this thesis, the ear probe for measuring OAEs is simply connected to the headphone jack. This allows the same smartphone to be used either with headphones for subjective hearing screening or with an ear probe for objective hearing screening by simply swapping the connected external hardware. This offers extensive hearing screening capabilities at an extremely low cost.

Finally, if the cost of the hearing screening system is low enough, it can be distributed by local governments or humanitarian aid organizations directly to schools and similar institutions. This would eliminate the need of logistics for returning and possibly calibrating these systems.

At Home Use by Laypersons

Hearing screening at home was recently enabled with subjective smartphone-based systems. This can be accomplished either by using ones own smartphone and headphones or by receiving a complete system via mail. The barrier of access for the former is quite low. However, it requires a decent pair of headphones and a suitable smartphone. The latter has the advantage of providing a “kit” that is potentially tested and calibrated, which allows a more precise hearing assessment. Similar to the smartphone-based institutional screening, these systems can also be equipped with OAE ear probes to measure OAEs for objective hearing screening. Smartphone-based hearing screening at home is predestined to be used in conjunction with telemedicine, especially when the next audiology specialist is far away or if contacts need to be reduced to avoid infections.

6.3 Concluding Summary

Hearing screening is the key for the timely detection and treatment of hearing loss. Coverage with hearing screening around the world is insufficient, especially with objective hearing screening tests, which are indispensable for early hearing loss identification in neonates and small children. The prevalence of hearing loss is higher in LMICs, compared to high income areas. At the same time, coverage with objective hearing tests in LMICs is further limited by the lack of financial resources and specialists. In this thesis, we investigated techniques for objective hearing screening systems that improve accessibility to hearing screening tests. The two primary goals were to lower the costs and to improve the usability for untrained users. Cost reductions were aimed at lowering the cost of manufacture as well as operation. Usability by laypersons was improved by simplifying the measurement procedures or building on well known platforms, such as smartphones, to which most people around the world are accustomed. At the same time, all techniques are presented relying on the well researched measurement of OAEs, which results in a high quality, comparability and acceptance from a clinical perspective. The main contributions of this thesis are summarized as follows:

Low-Cost Standalone OAE Hearing Screening System

We evaluated computational offloading for OAE-based hearing screening systems to a smartphone. The conclusion of this evaluation is that only a standalone or fully smartphone-based design is sensible. Based on the conclusions, we have successfully built a low-cost standalone objective hearing screening system. In its novel architecture, the ear probe is merged into the body of the device so that no cable is needed. The device can be used in a very similar manner to in-ear clinical thermometers, which simplifies preparation and execution of OAE measurements. Except for the ear probe tip, which is based on an existing OAE ear probe, all remaining parts are commercial of the shelf (COTS) components, which reduces cost. The software of the device is designed such that it can host future extensions and experiments. The device is capable of fully automated hearing screening tests with DPOAE and TEOAE on a single press of a button. We equipped the system with a near field communication (NFC) interface to exchange results and configuration data with a smartphone.

Ear Side Detection Based on Extra Sensors

To improve usability, we have equipped the low-cost standalone OAE hearing screening system with extra sensors to aid with the placement of probes. We ran a small study, where we measured TEOAEs in both ears of 10 adults. We recorded the data from extra sensors during the insertion of the ear probe and the actual OAE measurement. Based on the collected data, we have implemented a classifier that is able to discern in which ear, left or right, the probe was inserted, which can improve patient data entry and validation. The classifier using the capacitive sensor data could correctly identify the ear side in $75\,\%$ of the insertions, while the distance sensor-based classification could correctly identify all insertions in its preferred attitude.

Characterization of the Audio Subsystem of Android Smartphones

We identified smartphone-based objective hearing screening with minimal external hardware as another efficient approach. Most smartphones already include all relevant components that are needed to interface an OAE ear probe. The audio subsystem of smartphones provides the needed DACs, ADCs and their amplifiers. However, since the audio subsystem of smartphones is designed for phone calls and media playback, it was unclear whether smartphones are suited to stimulate OAEs and capture the minuscule OAE signals. We designed a passive adapter circuitry to connect an unmodified commercially available DPOAE ear probe to the headphone jack of smartphones. We implemented a network-based framework, including the app for Android smartphones, to remotely control the audio subsystem. We were able to conduct all smartphone measurements in this thesis without any hardware or software modification to the phones, but by using only the standard Android API. Our characterization results show that four out of seven tested smartphones are suitable to measure OAEs.

Smartphone-based Objective Hearing Screening Setup and Study

Based on the hardware/software setup and the characterization results of Android smartphones, we conducted a study with five adults, resulting in measurements in 10 ears. Using the four suitable smartphones and two commercial OAE measurement systems for reference, we thus conducted overall 60 measurements of TEOAEs and DPOAEs each. We extended our measurement framework such that one of the commercial measurement devices was remotely controlled by the same software framework as the smartphones. We found that two of the smartphones performed comparable to that existing measurement system, using the same software. Two more phones were also able to conduct hearing screenings, but were only able to detect the OAE at $6\,\mathrm{dB}$ less compared to the better performing devices. With this study, we showed that a fully device agnostic approach is not feasible. However, we were able to conclude that a low-cost hearing screening system is feasible using selected smartphones without modifications by only installing an app and connecting an OAE ear probe.

Simplified Single Speaker-based Probe Architecture

We proposed a novel probe design based on a single speaker for measuring TEOAEs, which exploits the separation of stimulus and OAE response in time domain. This probe architecture can potentially be manufactured at a cost of just a few Euros. Based on this approach, we built five prototype probes, each with a different model of speaker. We characterized the probes in a purpose built calibrator and found the frequency response of two of the probes appropriate. However, the suitable probes exhibited an extremely low sensitivity when recording at only $-80\,\mathrm{dB\,V/Pa}$ and $-67\,\mathrm{dB\,V/Pa}$, respectively.

Characterization and Drive Setup for Single Speaker-based Probes

The low sensitivity we found in the single speaker-based ear probes, as well as driving and recording from the same transducer in quick succession posed a major challenge for this ear probe architecture. We were able to design a measurement setup that was able to stimulate the speaker and record from the speaker membrane with a custom circuitry. We conducted measurements in an ear simulator, which showed promising results. Using this setup, we then measured TEOAEs in eight normal hearing adult ears. We were able show that these probes could detect TEOAEs in $71\,\%$ of all ears.

6.4 Future Work

The approaches discussed in this thesis show that there is a significant potential to improve the accessibility of objective hearing screening solutions. The techniques presented offer the possibility to lower the per unit cost of OAE-based hearing screening systems and, at the same time, are able to lower the barrier of usage. This allows untrained users to administer objective hearing screening tests with minimal prior knowledge. However, the engineering challenges to lower cost and improve the ease of use are only two aspects of improving the global coverage with comprehensive hearing screening. Besides these technical challenges, which form the main part of this thesis, other challenges exist. These include, on one hand, the actual manufacturing, distribution and maintenance of these devices. On the other hand, it is necessary that the general awareness and education surrounding the need and use of objective hearing screening is improved. This also implies providing the necessary financial resources for campaigns, training and allocation of hearing screening technology. However, these challenges are beyond the scope of this thesis, which focuses on the technical challenges of the objective hearing screening technology. In the remainder of this section, several open technical follow-up challenges are discussed and outlined.

Low-cost PCB-based Ear Probes

The performance of the ear probe is of central importance for any OAE measurement system. For the low-cost standalone device presented in Chapter 3, the design of a commercially available probe was adapted. In a following step, a custom ear probe should be designed, as to fully utilize the advantages of the novel system architecture, where the ear probe is merged into the device body. We propose a novel ear probe design that is based on surface-mounted device (SMD) transducers, which are preassembled on a PCB. The probe housing and acoustic channels would then be formed by half-shells that are pressed or glued to form the acoustic channels from the SMD to the ear probe tip. This design could use low-cost transducers, which are commonly used in consumer electronics like smartphones. Especially micro-electro-mechanical systems (MEMS) microphones have the potential to provide exceptional results at a remarkably low per unit cost. In addition to using low-cost transducers, this design would also remove the error prone manual soldering during assembly of the ear probe.

Implementation and Validation of Interactive Feedback using Extra Ear Probe Sensors

The low-cost standalone device was equipped with additional sensors at the ear probe. The sensor data was recorded during OAE measurements. In the work presented in this thesis, this recorded data was subsequently analyzed. The analysis aimed to detect in which ear, left or right, the measurement was taken. To fully utilize the data from the extra sensors, the data must be analyzed in real-time for interactive feedback to the examiner. This would allow to immediately assist the examiner when starting a new measurement procedure.

Additional to the ear side detection, other information might also be inferred from the extra sensor data. If a study with more data was conducted, one might be able to conclude information on the quality of the probe fit. In other words: Given the current readout from the extra sensors, can the success of the OAE hearing screening measurement be predicted? If such a link was to be found, the device could give interactive feedback to the examiner. This feedback could include information on how to adjust the probe or even which size probe tip to use. While a skilled examiner can probably do these adjustments based on experience, a layperson can profit from such a system and it might flatten the learning curve for unskilled examiners.

Improved Single Speaker-based Probe Drive Circuitry

The presented results in this thesis for the single speaker-based probes are based on a measurement setup using a high-end measurement hardware and sensitive low-noise amplifiers. A custom hardware needs to be designed, which replaces the expensive general purpose measurement hardware with low-cost circuitry. The current measurement principle is based on the superposition of the drive voltage, which is used to create the stimulus, and the voltage recorded from the speaker. The drawback of this technique is that some of the recording signal energy, and thus sensitivity, is lost. A follow-up hardware should be able to switch between a low impedance drive mode and a high impedance recording mode. However, this transition needs to be almost glitch free, as to not disturb the sensitive OAE signal, which is multiple orders of magnitude below the drive voltage.

Single Speaker-based Ear Probe Using In-ear Headphones

The single speaker-based ear probe design presented in this thesis is based on off-the-shelf speakers. The used speakers are typically found in mobile devices, e.g. smartphones and tablets. In the experiments, a custom 3D printed ear probe housing was manufactured for the speakers. In-ear headphones are similar to the single speaker-based ear probe: A single speaker is connected to the ear canal which is capped of using a soft tip material. A measurement system based on in-ear headphones as OAE probes would bring several advantages. The complete probe would be available as an off-the-shelf part, which is manufactured using a high degree of automation and established production processes. This lowers cost and, at the same time, can deliver the product at a constant quality level. Further, using in-ear headphone as foundation would make it economically sensible to offer the ear probe as a disposable single use item.

Single Microphone-based Ear Probe

Every single speaker-based probe suffers the same problem of low sensitivity and overall worse SNR compared to established OAE probe design. The presented work is based on a speaker which is also used as microphone. Some of the issues could be eliminated by basing the ear probe on the inverse principle: A microphone is used to record the response but also to generate the stimulus. This configuration would allow to utilize the optimal recording properties of microphones. Obviously, generating the stimulus at sufficient amplitudes would become the central problem. It would be conceivable to use either miniaturized condensers or dynamic microphones. The latter are possibly easier to drive as a speaker, since they are based on a similar principle, however, at a higher per unit cost. Condenser-based microphones need a rather high drive voltage to achieve the necessary sound pressure at the ear drum.

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Abbreviations

ABR	auditory brainstem response
ADC	analog-to-digital converter
AGC	automatic gain control
AN	auditory neuropathy
AP	action potential
API	application programming interface
AR	artifact rejection
ASCII	American Standard Code for Information Interchange
BLE	Bluetooth low energy
CAD	computer-aided design
CDMS	clinical data management system
CEOAE	click evoked OAE
CHL	conductive hearing loss
CMA	cumulative moving average
COTS	commercial of the shelf
CPU	central processing unit
DAC	digital-to-analog converter
dB	decibel
DC	direct current
DFT	discrete Fourier transform
DMA	direct memory access
DPOAE	distortion product OAE
DSP	digital signal processing
DUT	device under test
EEPROM	electrically erasable programmable read-only memory
ENT	ear, nose, and throat
EOAE	evoked OAE
EPL	emitted pressure level
FFT	fast Fourier transform
FIFO	first in, first out
FIR	finite impulse response
FM	frequency modulation

FoV	field of view
FPL	forward pressure level
FPU	floating point unit
GPIO	general-purpose input/output
HL	hearing level
HL	hearing loss
HMI	human machine interface
IC	integrated circuit
IEC	in-ear calibration
IHC	inner hair cell
IMD	intermodulation distortion
IMU	inertial measurement unit
IPC	inter-process communication
IR	infrared
ISR	interrupt service routine
I^2C	Inter-Integrated Circuit
I^2S	Inter-IC Sound
LCD	liquid crystal display
LDO	low-dropout
LED	light emitting diode
Li-ion	lithium-ion
LMIC	low and middle-income country
LPCM	linear pulse-code modulation
LTI	linear and time-invariant
MCU	microcontroller unit
MEMS	micro-electro-mechanical systems
NDEF	NFC Data Exchange Format
NFC	near field communication
NICU	neonatal intensive care unit
NIHL	noise-induced hearing loss
OAE	otoacoustic emission
OHC	outer hair cell
OLED	organic LED
OOM	order of magnitude
OS	operating system
Pa	Pascal
PC	personal computer
PCB	printed circuit board
peSPL	peak-equivalent SPL
PLL	phase lock loop
PMIC	power management integrated circuit
PTA	pure tone audiometry
QR	Quick Response

RAM	random access memory
RC	resistor-capacitor
RMS	root mean square
RTC	real-time clock
RTOS	real-time operating system
SD	Secure Digital
SD	standard deviation
SFOAE	stimulus frequency OAE
SIL	sound intensity level
SLA	stereolithography
SLM	sound level meter
SMD	surface-mounted device
SNHL	sensorineural hearing loss
SNR	signal to noise ratio
SOAE	spontaneous OAE
SPI	Serial Peripheral Interface
SPL	sound pressure level
SSOAE	synchronized spontaneous OAE
TCB	task control block
TEOAE	transient evoked OAE
THD	total harmonic distortion
ToF	time of flight
TRRS	tip-ring-ring-sleeve
TW	traveling wave
UNHS	universal neonatal hearing screening
USB	universal serial bus

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