

**VALIDITY ASSESSMENTS OF COMPUTERIZED AUDIOMETRY: A
CASE INVOLVING THE KUDUwave5000 AUDIOMETER AND THE
ACEScreening DEVICE**

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DECLARATION

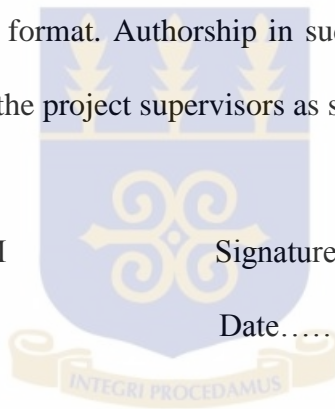
I **RONALD NKANSAH ADJEKUM** do hereby declare that this thesis which is being submitted in fulfillment of the requirements for the degree of Master of Science in Audiology is the result of my own research performed under supervision, and that except where otherwise other sources are acknowledged and duly referenced, this work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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DEDICATION

This work is dedicated to my late Father Adjekum, Kofi Boadu.



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LIST OF ABBREVIATIONS

iOS	iPhone Operating System
dB	Decibel
kdB	Kilo-decibel
dBHL	Decibel Hearing Level
dB SPL	Decibel Sound Pressure Level
Hz	Hertz
kHz	Kilo-Hertz
WHO	World Health Organization
ISO	International Standards Organization
AMTAS	Automated Method for Testing Auditory Sensitivity
SNR	Signal to Noise Ratio
ANSI	American National Standards Institute
KBTH	Korle Bu Teaching Hospital

ABSTRACT

Background: Technological progress in the construction of personal computers, has offered the possibility of conducting hearing tests with a computer program. Computerized audiometers can be designed for manual, automatic and self-administered hearing testing.

Aim: The study investigated the validity of the ACEScreening device as a self-administered hearing screening test and the KUDUWave5000 audiometer as an automated diagnostic audiometer.

Methods: The population for this study consisted of patients reporting to the audiology clinic in Korle Bu Teaching Hospital for hearing assessment and students of the College of Health Science, University of Ghana. Hundred subjects constituted the sample size. Subjects were selected based on an inclusion and exclusion criteria. The study was conducted at the audiology clinic in Korle Bu Teaching Hospital. Two laboratories with varying ambient noise were utilized. The first laboratory was a sound-treated booth (ambient noise < 40 dB). The second laboratory was a quiet office with an average ambient noise of 47.2 dB. The design employed for this study was a within subject experimental group design. Thus, each participant recruited into the study was tested with three audiometric equipments (a KUDUwave5000 audiometer in a quiet office, an ACEScreening device in a quiet office and a GSI 17 audiometer in a sound treated booth).

Results: There was a significant strong positive correlation between the unmasked pure tone air-conduction thresholds obtained by the KUDUWave5000 Audiometer in a quiet office and the same experiment obtained with the GSI 17 audiometer in a sound-treated booth across the frequencies of 250, 500, 1000, 2000 and 8000 Hz for right and left ears.

The mean differences revealed that the mean air-conduction hearing threshold difference between the GSI 17 audiometer and the KUDUwave5000 audiometer across each tested frequency for both right and left ears was less than 5dB.

There was a significant moderate to strong positive correlation between the unmasked pure tone air-conduction thresholds obtained with the ACEScreening device in a quiet office and the same experiment obtained with the GSI 17 audiometer in a sound-treated booth across the frequencies of 250, 500, 1000, 2000 and 8000 Hz for right and left ears. The mean air-conduction hearing threshold differences between the GSI 17 audiometer and the ACEScreening device was less than 17 dB at 250 and 500 Hz and less than 10dB at 1000, 2000, 4000 and 8000 Hz.

Conclusion: It is tenable that the ACEScreening device and the KUDUWave5000 can be used to conduct unmasked pure tone air conduction hearing test in a quiet office where the ambient noise is a little higher than the maximum permissible ambient noise levels for audiometric test environment.

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

The development of internet technologies combined with technological progress in the construction of personal computers, especially in terms of improving performance of sound cards, has offered the possibility of conducting self-administered hearing tests at home (Masalski & Kręcicki, 2013). According to Swanepoel and Biagio (2011) computerized or microprocessor audiometry supports novel applications including remote testing and automation that may improve the accessibility and efficiency of hearing assessment in various clinical and occupational health settings. These computerized audiometers can be designed for manual, automatic and self-administered (self-recording) testing. The KUDUwave5000 Audiometer, Otogram and smart phone applications designed for hearing tests are examples of computer-based audiometers.

1.1.1 Smart Phone Technology

Smart phones possess powerful microprocessors which can perform audiometric functions used in hearing assessment, and constitute powerful microprocessors that can be used to generate test signals delivered via sound output ports to the headphones for hearing testing (Kirkwood, 2013). Smart phones also have high quality video cameras that can be employed in video otoscopy while their USB ports can be utilized in the control of audiometric devices such as tympanometry, and hearing aid analyzers (Kirkwood, 2013).

Realization of the potential audiometric functions of smart phones has led to the development of appropriate smart phone applications that can be used to conduct hearing tests in a quiet

environment to meet the high demand for hearing healthcare especially in developing countries. Some of these applications include (1) ACEScreening application, (2) ACTION ON HEARING LOSS application and (3) the SIEMENS hearing test application.

1.1.1.1 ACEScreening Application

The ACEScreening application is a computerized self-administered hearing test designed for hearing screening. This application enables the user to perform a self-administered hearing test with a smart phone in a quiet room anytime. Routine hearing test results (audiograms) of the user can be housed in a database in a form of asynchronous tele-health and monitored over a period of time by a specialist for ototoxicity. The ACEScreening application is only supported on Android 2.3 or higher and iOS 5.0 or higher systems. The test condition is supported by an ambient noise less than 50dB, while the hearing test is conducted within a limited range of frequencies and intensities unlike the conventional manual audiometer. The test range of the ACEScreening application is presented in Table 1.1

Table 1: Test range of the ACEScreening application

Test Range	Frequency(Hz)					
	250	500	1000	2000	4000	8000
Minimum (dBHL)	-10	-10	-10	-10	-10	-10
Maximum (dBHL)	55	60	65	70	70	60

Source: www.acescreening.com

Auditory signals generated by the microprocessor of the smart phone are delivered into the external auditory canal of the user via a pair of ear buds, supra-aural (headphones worn over the ears) or circumaural headphones (headphones worn around the ears). The test application is specifically calibrated to Sennheiser HDA 205 headphones.

1.1.1.2 Sennheiser HDA 205 headphone

Figure 1 shows a Sennheiser HDA 205 headphone. It is a medium-sized supra-aural headphone with rotating ear cups, single-sided cable, 3.5 mm jack plug and 6.3 mm screw-on jack adaptor, and gold-plated. It has a frequency response range of 14Hz to 20kHz, a sound pressure level of 112 dB SPL, total harmonic distortion < 0.5 %, 206 g weight and a nominal impedance of 32 Ω . The electro-acoustic properties of the transducer make it capable of attenuating ambient noise, a characteristic suitable for pure-tone testing in the natural environment. All Sennheiser 200 series headphones have the same electro-acoustic characteristics.



Fig. 1.1: Sennheiser HDA 205 headphone (left) and ACEScreening application software interface (right).

1.1.2 KUDUwave5000 Audiometer

The computer-based air and bone conduction audiometer (KUDUwave5000) is an emerging technology aimed at increasing the efficiency of audiometric testing in varying environmental noise conditions. The KUDUwave 5000 audiometer is made up of insert earphones (ear phones placed in the ears), circumaural audio-cups housing an audiometer and a forehead bone

conductor placed with the aid of a head band and microphones which measure environmental sound (Swanepoel & Biagio, 2011). Figure 1.2 shows the KUDUwave5000 Audiometer and its software interface.

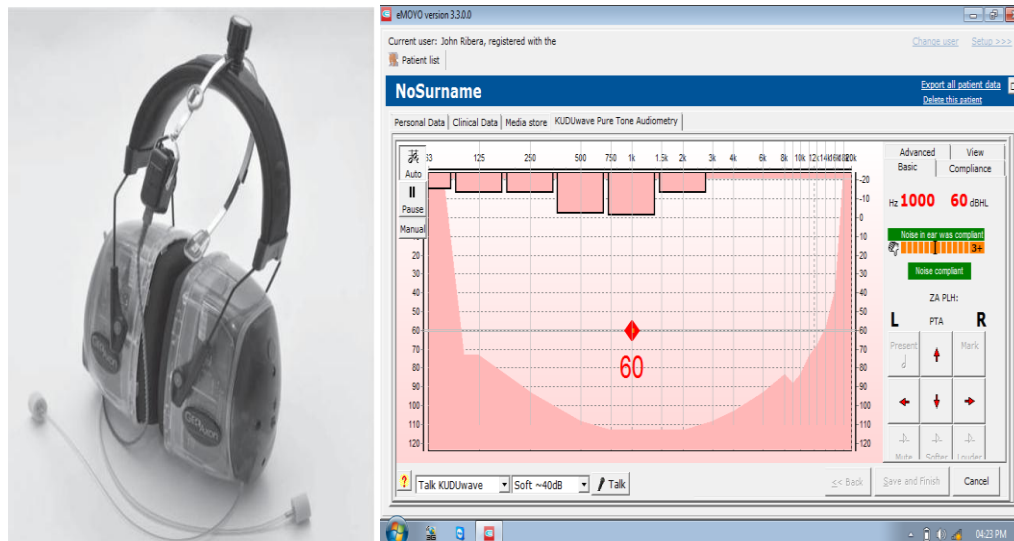


Fig. 1.2: KUDUwave5000 audiometer with its insert earphones and forehead bone vibrator (left). Source: MacLennan-Smith, Swanepoel and Hall III (2013) and the Software Interface for controlling the audiometer (right).

The insert earphones attenuate the effect of ambient noise on hearing threshold compared to supraaural headphones. The circumaural audio-cup housing together with a built-in damping material, also aids in attenuating ambient noise. The afore-mentioned framework is controlled by a software interface on a netbook lap-top computer (Swanepoel & Biagio, 2011). The ambient noise is depicted in the form of a sound spectrum on the software interface. The KUDUwave audiometer allows for testing to be performed either manually or automatically. During testing, the software interface displays the spectrum of ambient noise across each test frequency. This enables the tester to assess the ambient noise sound pressure levels and the possible effects on threshold.

1.2 STATEMENT OF THE PROBLEM

WHO has reported that 278 million people across the world have bilateral moderate to profound hearing loss, and the majority of the hearing impaired reside in developing countries. It is further estimated that 50% of the hearing losses are preventable in developing countries (WHO, 2008). In addition, global health reports have revealed that two-thirds of the world's least developed nations are in Sub-Saharan Africa and accounts for 10% of the world's population (WHO, 2008). The WHO report further indicated that over 1.2 million of children in Sub-Saharan Africa within the age bracket of 5 to 14 years have bilateral moderate- to-severe hearing loss (WHO, 2008).

The prevalence of hearing loss in Sub-Saharan Africa children ranges from 2.2% to 9.2% (Hatcher, et al, 1995; Frets-van Buuren, et al, 1990). Lasisi, Ayodele and Ijaduola (2006) suggested that the causes of infant hearing loss were measles (13.6%), meningitis (7.8%), viral infections (24.3%) and ototoxic medications which also include the use of drugs in damaging doses (12.6%). In Ghana, with respect to Africa, the prevalence of hearing loss is between 7-10% (Essel, 1999; Amedofu et al, 2006). However, Marfoh (2011) reported a prevalence of 22.5% among the inhabitants of Offinso, a town in Ghana and indicated that noise and presbycusis were the main causes of sensorineural hearing loss while ear wax and otitis media constituted the main causes of conductive hearing loss in Ghana.

Access to hearing health care is a major challenge to the hearing impaired in Ghana, due largely to the dearth of hearing health care professionals, especially audiologists. According to the National Institute on Deafness and other Communicative Disorders (NIDCD) the way forward to increasing accessibility and affordability of hearing healthcare for adults with mild-to-moderate forms of hearing loss is to adopt innovative and creative solutions such as smart phone-based hearing screening systems (NIDCD, 2009). These innovative approaches are often in the form of

computerized technology compared to the conventional manual method of hearing assessment. The study considers these innovative computerized technologies as the most appropriate means of extending and developing hearing health care in developing countries.

Krumm (2010) posits that despite the enormous advantages of computerized audiometers, they appear to suffer from questionable calibration, poor validation and lack of control over ambient noise which must be abated either through environmental or headphone solutions. Coleman (2011) suggests that there is lack of validation regarding the use of smart phones in hearing screening. Poor validation of audiometric equipments leads to increment in false negative and positive results. It also leads to the inadequate verification of results. The major effect of poor validation of audiometric equipments is wrong audiometric assessment and management. Validation of audiometric equipment includes calibration. Audiometric equipment cannot be considered reliable merely on the guarantee of its manufacturers. The equipment is valid and reliable after producing a consistent output over a period of time. Therefore, it is important that varying approaches are applied to establishing the validity and reliability of audiometric equipment prior to use in either clinical, research or industrial setting.

1.3 AIM OF THE STUDY

The study investigated the validity of the ACEScreening device as a self-administered hearing screening test and the KUDUwave5000 audiometer as an automated diagnostic audiometer.

1.4 OBJECTIVES OF THE STUDY

The defined specific objectives of the study were:

- To examine the effect of ambient noise on the output (hearing thresholds) obtained by the KUDUwave5000 audiometer and the ACEScreening device
- To determine whether the hearing thresholds obtained by the KUDUwave5000 audiometer and the ACEScreening device in a quiet office were comparable to hearing thresholds obtained with the conventional manual audiometer in a sound- treated booth. In particular, a quiet office is an office with an ambient noise of 50 dB and below

1.5 STATEMENT OF HYPOTHESES

In line with the stated specific objectives of the study, the following hypotheses were set and tested.

- H₁: there will be a significant strong negative correlation between the unmasked pure tone air-conduction thresholds obtained by the KUDUwave5000 Audiometer in a quiet office and the same experiment obtained with the GSI 17 Audiometer in a sound-treated booth (gold standard) across the frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz for right and left ears.
- H₂: there will be a significant strong negative correlation between the unmasked pure tone air-conduction thresholds obtained with the ACEScreening device in a quiet office and the same experiment obtained with the GSI 17 audiometer in a sound-treated booth (gold standard) across the frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz for right and left ears.

1.6 SIGNIFICANCE OF THE STUDY

This study can be used as a baseline as well as enhancing steps in educating the public in Ghana and the Sub-Saharan African regions and health professionals about the use of innovative

technologies in audiology (computerized audiometry). It can also assist policy makers in Ghana and Sub-Saharan Africa to adopt innovative technology in expanding hearing health care to remote areas. Furthermore, the study can serve as another step for researchers to build on a comprehensive method of assessing the validity of computerized audiometers and brainstorming ideas to further develop these technologies. The study can serve as reference material for researchers, policy makers etc to broaden their knowledge base on the use of innovative technology in expanding hearing health care. It can educate and sensitize the public about the 'baby profession' audiology, in Ghana.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

The Chapter is categorized into three main sections. These include the conceptual framework of the study, the theoretical framework and review of related studies.

2.2 CONCEPTUAL FRAMEWORK OF THE STUDY

From fig. 2.1, the conceptual framework of the study is a comparison of the audiometric outputs of the KUDUwave5000 audiometer and the ACEScreening device in a natural environment (quiet office) with the outputs of the conventional audiometer in a sound- treated booth (Gold Standard).

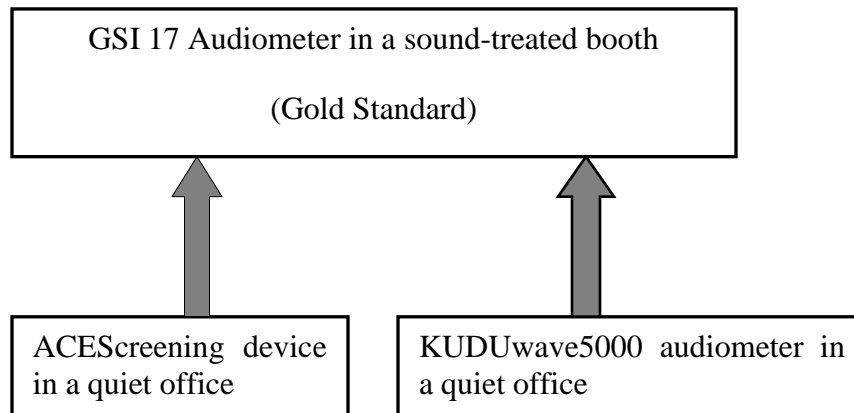


Fig. 2.1: A block diagram showing the conceptual framework of the study

2.3 THEORETICAL FRAMEWORK

The theoretical framework of this study was constructed on the basis of previously propounded concepts/theories. The concept of masking (background noise) and loudness perception

(sensitivity of the human ear as a function of frequency) constituted the basic framework of the study.

2.3.1 Masking (Concept of Background Noise)

Masking is the effect by which the simultaneous presence of one sound interferes with the detection of another (Loven, 2010). Background sound can change the audibility of target sounds depending on the spectral content of the background noise. Loven (2010) conceived that if the spectral content of the masker (background noise) is not restricted, maximum masking will occur within the most sensitive hearing region. On the other hand if the spectral content of the background noise is narrow or restricted (e.g. pure tones), maximum masking effects will occur when the spectral characteristics of the masker and the signals are similar. The effect of background noise on auditory sensitivity is presented in Fig. 2.2

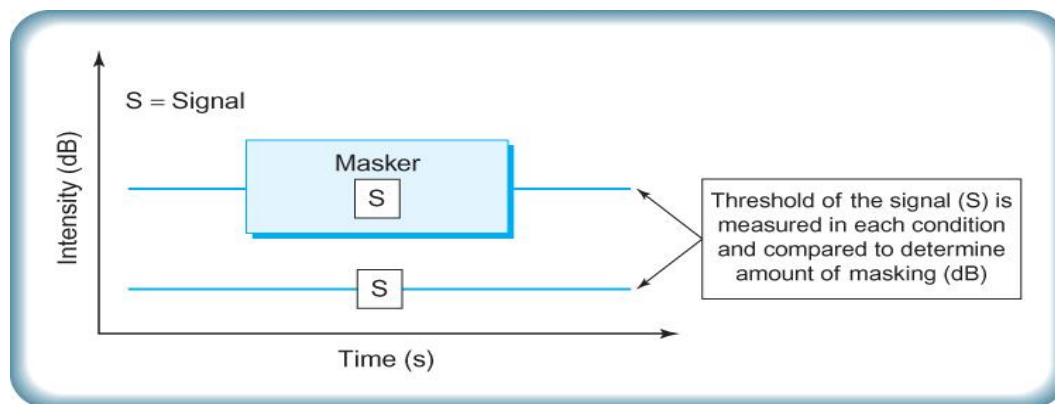


Fig. 2.2: A paradigm depicting the effects of masking. Source: Loven (2010)

As indicated in Fig. 2.2, in order to determine the effect of background noise on the threshold (hearing level) of a signal the threshold of the target sound or signal in quiet (without background noise) is compared to the threshold of the signal in the presence of background noise. The change or shift in audibility (threshold) of the signal or target sound is determined by

a difference between the thresholds of the afore-mentioned conditions expressed in dB. It is expected that the presence of background noise will either lead to an increase in threshold or hearing level (audibility level) of the target sound or have no effect on the target signal.

2.3.2 Loudness Perception

Loudness perception is the sensitivity of the human ear as a function of frequency. The shape of the contours in Fig. 2.3 illustrates the effect of frequency on loudness perception.

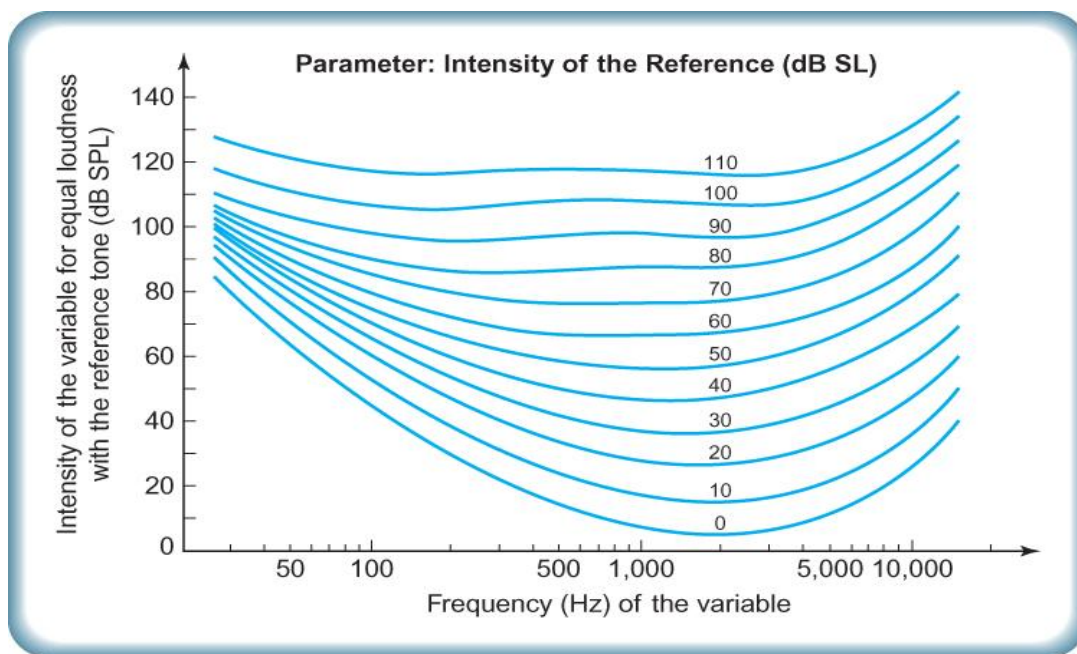


Fig.2.3: Equal loudness contours depicting the loudness perception of sound at various intensities as a function of frequency. Source: Loven (2010)

Figure 2.3 reveals that an intensity of sound is perceived relatively louder at the mid frequency range (700 to 5000 Hz) than at the low (< 700 Hz) and high (> 5000 Hz) frequency ranges. This implies that in order to maintain a constant loudness across all frequency ranges, the intensity of the sound at the mid frequency range should be decreased. The differences in the loudness perception of sound as a function of frequency is due to the fact that some of the hair cells of the basilar membrane respond to some frequencies of sound with a greater amount of neurological

activity than others. This phenomenon is more evident in the mid frequencies and accounts for the shape of the contours in Fig. 2.3.

2.4 REVIEW OF RELATED STUDIES

2.4.1 Validity of Conventional Manual Audiometry in the Natural Environment

Karlsrose, et al (1998) ascertained the validity of pure-tone audiometry performed in a quiet office by comparing it with diagnostic pure-tone audiometry performed in a standard booth that conformed to International Standards Organization (ISO) standards. One hundred and nineteen participants were tested in the two conditions using a single-blinded crossover design. The participants were tested across the frequencies of 250,500,1k, 2k, 3k, 4k and 8k Hz for only air-conduction thresholds after passing an initial otoscopic examination. The study concluded that pure-tone air conduction audiometry with the appropriate calibration can be performed in a generally quiet environment without referring for an audiological examination.

2.4.2 Validity of Computerized Manual Audiometry in the Natural Environment

Swanepoel and Biagio (2011) conducted a study on the validity of a computer-based audiometer (KUDUwave5000) for air and bone conduction (forehead) by comparing its audiometric findings with the findings of a conventional industry audiometry standard. Thirty subjects within the age bracket of 19-77years participated in the study. The agreement between the two conditions was ≤ 5 dB for air conduction thresholds between the 2 audiometers in more than 90% of cases with an average absolute difference of 3.5dB (3.8 SD) at a confidence interval of 95% (2.6dB to 4.5dB). In addition, bone conduction thresholds agreed on average within 10dB or less in 92% of cases. The average absolute difference was 4.9dB (4.9 SD) at a 95% confidence interval (3.6dB to 6.1dB). Furthermore, the study measured test-retest reliability for the industry standard

audiometer and the computer-based audiometer. The findings established a normal test-retest reliability within the limits of industrial standard audiometry.

MacLennan-Smith, et al (2013) investigated the validity of the diagnostic KUDUwave5000 in a natural environment. Both air-conduction and forehead bone-conduction thresholds were measured in the natural environment at 250 to 8000 Hz and 250 to 4000 Hz respectively and compared with thresholds measured in a sound-treated booth across the same frequencies. In this within-subject experimental group design, 147 adults with an average age of 76 ± 5.7 years were involved. The hearing of the participants was assessed prior to the study. The results indicated that air-conduction thresholds corresponded within 0 to 5 dB in 95% of all comparisons between the various test environments. Further, bone-conduction thresholds corresponded to within 0 to 5 dB in 86% of comparisons. Average threshold differences of ± 0.6 to 1.1 and standard deviations (3.3 to 5.9) were within typical test-retest reliability limits. In conclusion, there was no statistically significant difference in the threshold recorded across all the frequencies for the two test conditions except at 8000Hz. The study concluded that the KUDUWave audiometer can be used for valid diagnosis in environments or conditions where there are no sound-treated booths.

A study to determine the effect of ambient noise on the validity of thresholds obtained by the KUDUwave audiometer by comparing with thresholds obtained using the GSI-61 clinical audiometer in a sound-treated booth was investigated by Storey, et al (2014). A total of 31 subjects were tested in three experimental conditions for pure tone air-conduction thresholds including (1) testing with a clinical audiometer in a quiet sound booth (2) testing with the KUDUwave in a quiet sound booth and (3) testing with the KUDUwave with 40 dBA of ambient noise. The results of the study showed that 89% of air-conduction thresholds obtained by the

KUDUwave in quiet, and 92% of thresholds obtained by the KUDUwave in background noise were within 5 dB of air conduction thresholds obtained with the clinical audiometer. The accuracy of the KUDUwave audiometer was reported to be poorer at 250Hz and 8kHz. The study concluded that the KUDUwave may be reliable for testing in the absence of a clinical audiometer in a sound-treated booth.

2.4.3 Validity of Computerized Automated Audiometry

Henry, et al (2001) ascertained the test-retest reliability of hearing thresholds obtained by a computerized automated tinnitus matching technique and Etymotic ER-4B Canal Phone™ insert earphones. Repeated measurements of hearing within and between sessions, and the effect of eartip removal and reinsertion constituted the study design. Using a precision of 1-dB, 20 normal hearing participants were tested (0.5-16kHz) in two sessions with an automated protocol. There was an initial testing without removing the eartips, then after eartip removal and replacement. Hearing thresholds between the two sessions differed by an average of 2.5 dB across all tested frequencies and 98.1% of the repeated measures (thresholds) were within ± 10 dB. The study concluded that eartip removal and replacement did not have an effect on hearing thresholds.

Swanepoel, et al (2010) conducted a study on 38 subjects (30 normal hearing and 8 hearing impaired) to ascertain the reliability, accuracy and time efficiency of automated audiometry. Air conduction thresholds across the frequencies of 125-8000Hz were determined manually and automatically. Subjects were counterbalanced. Pure-tone air-condition tests were repeated to ensure test-retest reliability for the normal hearing participants in manual and automatic mode, and also for the recording time. The results indicated that the two conditions (manual versus automated) were not significantly different from each other in terms of test-retest reliability. In

addition, the thresholds for the test conditions did not differ significantly from each other and the two conditions were equally time efficient. The study concluded that automated threshold seeking is reliable, accurate and time-efficient with respect to hearing assessment in both the normal-hearing and the hearing-impaired.

Margolis, et al. (2010) also investigated the validity of the automated method of obtaining an audiogram using the Automated Method for Testing Auditory Sensitivity (AMTAS) which is based on a single-interval, yes-no, psychophysical method with feedback. The study incorporated findings from three different studies on the validity of AMTAS for both air and bone conduction thresholds with masking stimulus presented to the non-test ear. The first study involved the manual testing of six participants at three different settings by two audiologists at each test setting. The mean difference between the outputs of the test obtained by the paired audiologist provided a standard of reliability for the gold standard audiometry.

The second study involved the testing of 30 participants with 5 normal hearing individuals and 25 hearing impaired using AMTAS versus the gold standard audiometry. It was observed that the inter-tester differences of the air-conduction thresholds of the two test methods were similar to the inter-tester differences of the air-conduction thresholds of the first study. However, the inter-tester differences of the two test methods for bone conduction thresholds varied significantly with respect to the inter-tester difference for study 1. Two possible causes of variability were identified: incorrect reference-equivalent threshold force levels for forehead bone conduction and a differential effect of middle-ear disease on forehead and mastoid bone-conduction thresholds. Finally, the third study compared inter-subject variability for forehead and mastoid bone-conduction thresholds. The results indicated significant variability.

Margolis & Moore (2011) examined the occlusion effect produced by circumaural, supra-aural, and insert ear phones at the same time comparing air and bone conduction thresholds obtained with the conventional manual (gold standard) audiometer and AMTAS. Participants with sensorineural hearing loss were utilized. Initially, six adults who passed otoscopic and middle ear examinations were participants for an acoustic and psychoacoustic occlusion measurement. These measurements were compared with the gold standard and AMTAS air-and-bone conduction thresholds. Further, the thresholds of 19 ears of 13 participants with sensorineural hearing loss were obtained with pure-tone audiometry. The results indicated that, the supra-aural earphone produced the largest occlusion effects. This was followed by the insert earphone. The circumaural earphone produced the least occlusion effect. The study concluded that a systematic difference in air conduction threshold was due to earphone differences for the gold standard and AMTAS procedures.

Margolis, et al (2011) examined the validity of AMTAS in children between the age brackets of 4 to 8 years. A group of adults were also tested to serve as a control group. A quality assessment method, QUALIND was used to determine the accuracy of the test. The sample size consisted of 81 children and 15 adults with majority of the sample having normal hearing. Only air conduction thresholds were obtained. The results indicated that the inter-tester differences between two audiologists were similar to the inter-tester differences between the manual and AMTAS method. QUALIND had a sensitivity of 71% and a specificity of 91% for inaccurate audiograms. The study concluded that AMTAS is capable of reducing cost and increasing efficiency and accessibility to hearing assessment when applied in audiometry.

Mahomed, et al (2013) conducted a meta-analysis on the validity of computerized automated audiometry compared to conventional manual audiometry, using reviewed databases such as MEDLINE, SCOPUS and PUBMED. In particular, 29 studies designed using within-subject experimental comparisons of manual versus automated audiometry and which satisfied defined inclusion criteria were included. Weighted mean differences and standard deviation outcomes of the utilized studies were analyzed to make conclusions on the validity of automated audiometry versus the gold standard/conventional manual audiometry. The results provided limited data on children and bone conduction status. Further, test-retest reliability for automated audiometry in the meta-analysis was normal. The study concluded that though automated audiometry provided valid or accurate measures of hearing, there were, however, limited data on (a) automated bone conduction audiometry, (b) automated audiometry in children and difficult-to-test populations and (c) different types and degrees of hearing loss.

Another study to determine the accuracy of an Apple iOS-based automated hearing testing application by comparing with a conventional audiometry was ascertained by Foulad, et al. (2013). Forty-two subjects underwent three experimental conditions including: (1) automated iOS-based hearing testing in a sound booth, (2) automated iOS-based hearing testing in a quiet room, and (3) conventional manual audiometry. The results showed that 96% of the threshold values obtained using the automated test in a sound booth were within 10 dB of the corresponding threshold values obtained using conventional audiometry. Ninety-four percent of the threshold values of automated test performed in a quiet room were within 10 dB of the threshold values obtained using conventional audiometry. The study concluded that the hearing test application yield hearing test results that approach those of conventional audiometry.

Convey, et al (2014) investigated whether a combination of automatically administered pure-tone audiometry and a tone-in-noise detection task, delivered via an air conduction pathway, could reliably and validly predict the presence of a conductive component to the hearing loss. A secondary objective was to determine the reliability and validity of a novel automatic audiometry algorithm. A total of 120 ears (normal-hearing and conductive, sensorineural, and mixed hearing-loss subgroups) underwent three test conditions in a randomized order: (1) manual pure-tone air conduction audiometry and bone conduction audiometry; (2) automatic pure-tone air conduction audiometry; (3) and an automatic tone-in-noise detection task. There were repeated measures for the automatic tests. The study reported that ears with a conductive component (conductive and mixed ears) tended to have normal signal to noise ratios despite impaired thresholds in quiet, while ears without a conductive component demonstrated, on average, an increasing relationship between their thresholds in quiet and their achieved Signal to Noise Ratio (SNR). Furthermore, the individual automatic tests comprising the battery were found to be reliable and valid, with strong, significant correlations between the test-retest results. The study concluded that the presence of an air-bone-gap can be predicted with a reasonably high degree of accuracy using air-conduction tests alone. The Application of such test battery includes any setting in which bone conduction audiometry or specialized diagnostic equipment is unavailable.

2.4.4 Validity of Computerized Self-Administered Audiometry

Another study to determine the validity of the Otogram, a self-administered audiometer in an otology out-patient department was conducted by Ho, et al (2009) using a sample size of 48 patients and two experimental conditions. The first condition involved pure-tone audiometry performed by an audiologist while the second condition involved a pure-tone audiogram

obtained with the Otogram (self-administered). The results indicated that the level of agreement in air-conduction and bone-conduction thresholds between the audiologist and the Otogram on the same patient was equivalent to the inter-rater level of agreement between pairs of audiologists. The work affirmed that the Otogram was just as reliable as audiologists at determining hearing thresholds.

A study to investigate the accuracy and consistency of an internet-based self-administered hearing test using clinical pure-tone air-conducted audiometry as gold standard was conducted by Louise, et al (2010). Seventy-two subjects (52 normal hearing 20 hearing impaired) within the age range of 19 to 71 years participated in the study using a within-subject experimental group design. The Pearson correlation coefficient for the two test methods was 0.94 ($p < 0.0001$) for the right ear and 0.93 for the left ($p = 0.0001$). The greatest mean differences were observed at 2 and 4 kHz (-5.6 dB and -5.1 dB respectively). The sensitivity and specificity for hearing loss was 75% and 96% respectively. Test-retest reliability was excellent, with a Pearson correlation coefficient of 0.99 for both ears. The study concluded that it is viable to assess hearing with reasonable accuracy using an Internet-based hearing test on a personal computer with headphones. However, the feasibility of self-administered hearing test in participants' homes needs further investigation.

In another work performed on 28 difficult-to-test-patients, Yu, et al (2011) assessed the validity of the Otogram by comparing with audiograms obtained by an audiologist. The study participants were subjected to three experimental conditions. Two of the conditions included obtaining an audiogram by an audiologist while the remaining condition included obtaining an

audiogram via the Otogram. Audiograms obtained by the audiologist were first compared to obtain test-retest reliability. The audiograms obtained by the audiologist were then compared with the audiograms obtained using the Otogram. The audiograms were compared to determine if the thresholds across the tested frequencies agreed within 10 dB. The results indicated a high level of agreement evidenced by the fact that more than 90% of air and bone conduction thresholds were within 10 dB. It was established that the Otogram had a great potential as a diagnostic device in improving access to hearing health-care.

Kam, et al (2012) ascertained the reliability and validity of a self-administered hearing test application running on a smart phone. A within-subject experimental group design was used in the study. One hundred Chinese adults participated in the study which involved two experimental conditions. The first condition constituted the audiometric assessment of participants in a sound-treated booth. The second condition comprised an air-conduction threshold test with the self-administered device in a quiet room with an average ambient noise of 41 dBA. The results revealed high test-retest reliability for repeated measurements conducted with the self-administered device and established no significant difference between the thresholds measured with the self-administered device in the quiet room and the standard audiometry in a sound-treated booth. The study concluded that the self-administered application (computerized self-administered audiometry) was as reliable as the standard pure-tone audiometry.

A study to determine the measurement error and validity of the hearing thresholds of self-administered web-based pure-tone audiometry was conducted by Masalski and Kręćicki (2013). In particular, the study sought to assess and describe the factors that influenced the output of the audiometric device. Fifty-one patients from the outpatient department of an audiology clinic

constituted the sample size of the study. The study was comprised of three experimental conditions. The first condition included hearing tests with a clinical audiometer. The second condition involved self-tests done on a specially calibrated computerized audiometer under the supervision of an audiologist. The final experimental condition involved self-administered tests conducted at home. Thirty seven (73%) participants out of the 51 who participated in the first two experimental conditions were selected for the third condition. The study concluded that web-based pure-tone audiometry was applicable in screening exercises.

van Tasell and Folkeard (2013) investigated the reliability and validity of a method of self-measurement of pure-tone air-conduction thresholds using an iPad, automated instructions and with minimal supervision. Fifty-five adults with at least a unilateral hearing loss from mild-to-severe constituted the sample size. The study was conducted in research laboratories and audiology clinics at a university. A software-controlled method and a self-administered method of adjustment, both loaded on an iPad with standard audiometry transducers constituted the experimental laboratory. The results indicated that the average automated versus manual threshold differences were within the range of inter-tester variability for manual audiometry. It was concluded that the iPad self-test methods yielded accurate and reliable results.

2.4.5 Significance of Supra-aural, Insert and Circumaural Transducers in Pure Tone Audiometry

A study performed by Wright and Frank (1992) investigated the attenuation values for a supra-aural earphone and insert earphone using 1/3 octave band noise as the test signal in a reverberant chamber. Seventeen children using insert and supra-aural headphones and 10 adults using insert headphones constituted the sample for the study. The study concluded that the insert phones used

in the study provided maximum attenuation and could be used to conduct audiometric testing in higher ambient noise than the maximum permissible ambient noise levels provided by ANSI S3.1-1991.

Another study by Frank and Williams (1993) ascertained the effect of background noise on earphone thresholds via the use of real-ear attenuation at thresholds and mon-aural pure-tone test thresholds for normal hearing individuals. The transducers utilized in the study included a supra-aural headphone, an audio-cup and an insert headphone. The experiment was conducted in quiet and noisy conditions to obtain hearing thresholds. In particular, Frank and Williams (1993) study concluded that the insert earphone provided the maximum attenuation.

2.4.6 Significance of Non-Clinical Transducers in Pure-tone Audiometry

Schmuziger, Probst & Smurzynski (2004) also examined the test-retest reliability of pure tone thresholds from 500 Hz to 16000 Hz by comparing the hearing thresholds of 138 normal hearing subjects tested with Sennheiser HDA 200 and Etymotic Research ER-2 transducers using a repeated measures design. The results of the study indicated that there were no significant differences in repeatability for the two transducer types for all frequency ranges and that the two transducers were consistent.

Another study by Jonas and Johannes (2010) evaluated inter-aural attenuation (IA) for pure-tones ranging from 125 to 1600 Hz using Sennheiser HDA 200 circumaural earphones and Telephonics TDH-39P earphones. The findings indicated that the HDA 200 earphones provided a relatively higher IA than the TDH-39P, especially at frequencies lower than 500 Hz. It was concluded that contralateral masking should be applied to the non-test ear during pure-tone

audiometry with the HDA 200 earphones when the level at the test ear is more than 40 dB above the threshold of the non-test ear.

Lo and Bradley (2013) conducted an investigation to examine the utility of noise-cancelling headphones in school hearing screening programs by comparing the pure-tone air conduction audiometric results obtained with PXC4450 circumaural headphones and TDH-39 supra-aural earphones (gold standard). A sample of 232 school children within the age bracket of 6 to 8 years was screened by 30 dBHL and 25 dBHL criteria from 500Hz to 4000Hz. Statistically significant differences were found at 500 Hz for both 30 dBHL and 25 dBHL criteria, and at 1000 Hz and 2000 Hz for 30 dBHL criteria. However, further analysis between the same transducers using the mean thresholds revealed a high level of agreement. The study concluded that noise cancelling headphones may be used in screening at lower intensities.

2.4.7 Pure Tone Air Conduction Hearing Threshold Variability

Hearing thresholds are often obtained with the conventional 10dB down and 5dB up method in most reliability studies. According to Hickling (1964), many studies have reported a good reliability of test-retest threshold measurement. This assertion is also supported by Tyler, et al (1980). Newby (1972) suggested that the application of the 5 dB step in reliability studies has led to the consideration of the variability of hearing thresholds to be approximately 5 dB. On the contrary, studies with self-administered audiometry using 1 dB step have reported relatively more sensitive thresholds compared to manual audiometry (Lutman et al, 1989). Stuart, et al (1991) posits a test-retest limit of 5 dB for air conduction thresholds in a study to ascertain the test-retest variability in audiometric threshold with supra-aural and insert earphones among children and adults. Smith-Olinde, et al (2006) also suggests a test-retest limit of 5 dB for air-

conduction thresholds in a study to investigate test-retest reliability of in-situ unaided thresholds in adults. Ho, et al (2009) reported an inter-tester variability of 10 dB in a study to ascertain the validity of computer-assisted audiometry.

Swanepoel, et al (2010) reported an average absolute difference in air-conduction thresholds as a function of frequency (25kHz to 8kHz) for all ears between automated and manual pure-tone audiometry of 2.4 dB. While Margolis, et al (2010) reported an absolute average difference of 3.6 dB, Kam, et al (2012) published an absolute average difference of 6.3dB in air conduction thresholds for all frequencies and ears between a computerized self-administered hearing test and a conventional manual audiometry. In conclusion, the literature on the validity of computerized audiometers revealed an acceptable variability of air conduction thresholds from less than 5 dB to 10 dB.

2.5 RESEARCH GAP

Although a significant number of studies have been conducted to evaluate the validity of computerized audiometry (Ho, et al, 2009; Swanepoel, et al, 2010; Margolis, et al, 2010; Swanepoel & Biagio, 2011; Margolis, et al, 2011; Kam, et al, 2012; Mahomed, et al 2013; MacLennan-Smith, et al 2013; Masalski, et al, 2013; Van Tassel, et al, 2013..), there are limited data on computerized bone-conduction audiometry, computerized audiometry in children and difficult-to-test populations (Mahomed, et al, 2013). There are also limited studies on the validity of self-administered hearing test applications. It is based on this necessity that the current study was designed to investigate the validity of computerized audiometry, especially, smart phone-based self-administered audiometry.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This Chapter provides a comprehensive method on how the stated specific objectives were achieved.

3.2 STUDY DESIGN

The design employed for this study was a within-subject experimental group design. This design was suitable in achieving the stated specific objectives of the study. There was one independent variable, and one dependent variable. The independent variable constituted the type of test instrument (conventional manual GSI 17 audiometer, the KUDUwave audiometer and the ACEScreening device), while the air-conduction thresholds constituted the dependent variable

3.3 SAMPLE POPULATION

The population for this study consisted of patients reporting to the audiology clinic in Korle Bu Teaching Hospital (KBTH) for hearing assessment and students of the College of Health Sciences, University of Ghana. One hundred subjects represented the sample size. Subjects were selected based on inclusion and exclusion criteria.

3.4 INCLUSION AND EXCLUSION CRITERIA

3.4.1 Inclusion Criteria

Participants involved in the study were at least 8 years old. This criterion was set because most participants aged below 8 years could not accomplish the series of tasks required to perform a

self-administered hearing test with the ACEScreening device in the pilot phase of the experiment.

3.4.2 Exclusion Criteria

Participants with any condition which did not allow for pure tone testing were excluded from the study. Patients with a degree of hearing loss greater than a moderate loss after an initial assessment were excluded. This criterion was set due to the test range of the ACEScreening device.

3.6 STUDY SITE

The study was conducted at the Hearing Assessment Clinic in KBTH. Two laboratories with varying ambient noise consisting of a sound-treated booth (ambient noise < 40 dB) and a quiet office with an average ambient noise of 47.2 dB were utilized.

3.7 SAMPLING METHOD

A convenience sampling technique was used in recruiting participants into the study because it offered easy accessibility to research participants.

3.8 INSTRUMENTS AND MATERIALS

A GSI 17 Audiometer with TDH49 headphones in a sound-treated booth was used for unmasked manual pure-tone air-conduction testing. The GSI 17 Audiometer was calibrated with a Larson-Davis 824 Sound Level Meter (Larson Davis, Provo, Utah) in accordance with ANSI S3.6 2004, and a 6cc coupler. A KUDUwave5000 Audiometer, within calibration with insert foam tips was employed in unmasked automated pure-tone air-conduction testing.

An i-Pad 3, model MC707LL/A with iOS version 7.0.4(11B554a), supporting an ACEScreening application calibrated to a pair of Sennheiser HDA 205 headphones was also employed in conducting unmasked self-administered pure-tone air-conduction hearing test. A Welch-Allyn otoscope, a GSI Tymptstar middle ear analyzer and an Interacoustics AC 33 Audiometer were utilized in completing a full audiological assessment. Figure 6 presents the Larson-Davis set utilized in the calibration of the conventional manual audiometer (gold standard)



Fig.3.1: Larson-Davis 824 Sound Level Meter, 6cc coupler and a 500 gram load. Source: NASED Handbook (2012).

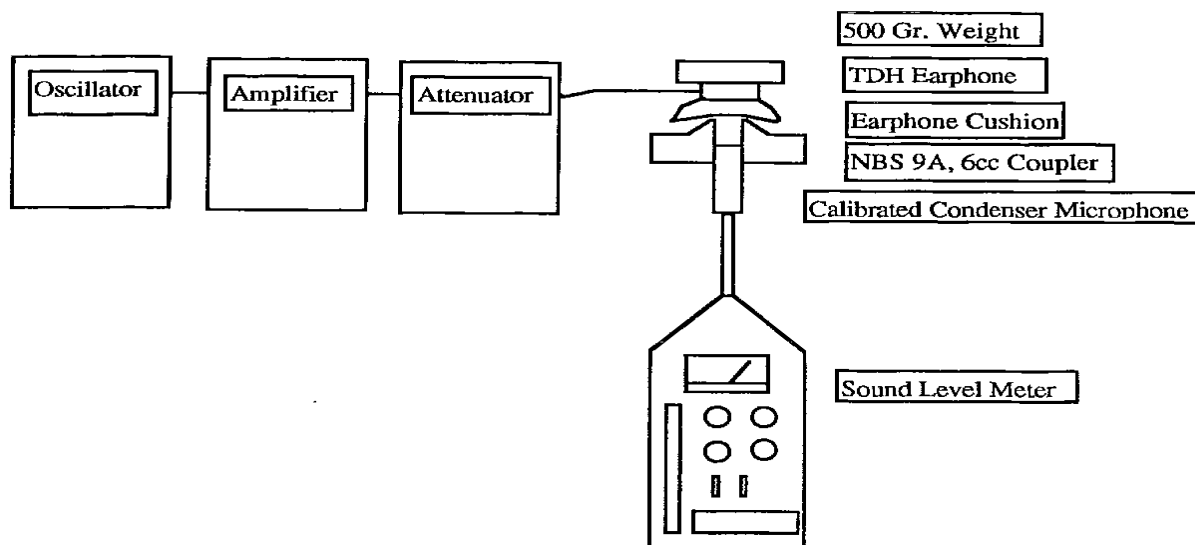


Fig. 3.2: A block diagram depicting the calibration of audiometer

Furthermore, noise spectrums were measured with a real-time analyzer of Studio Six Digital Professional Audio Tools 5.5 loaded onto an iPad 2, using an iAudioInterface2 as the audio input device with an AudioControl CM145 microphone (microphone has passed ANSI S1.4-1983 and IEC 61672-3 Type 1 Sound Level Meter Certification).

3.9 PROCEDURE FOR DATA COLLECTION

The GSI 17 Audiometer with Telephonics TDH49 headphones in a sound-treated booth was calibrated comprehensively two weeks prior to data collection. Comprehensive calibration included output level, frequency, distortion and linearity. Biologic calibration of the GSI 17 audiometer, KUDUwave5000 audiometer and the ACEScreening device were carried out 30 minutes on each day before data collection.

The experimental protocol began with a completion of a history and an informed consent form for each participant. Information on the demographics of participants was also recorded. This was followed by the education of participants on the study. A full audiometric assessment consisting of an otoscopic examination, impedance audiometry and pure-tone-audiometry was performed for each participant. The next task included unmasked pure-tone-air conduction testing in three experimental conditions:

- (1) Unmasked manual air-conduction pure-tone testing with the GSI 17 Audiometer in a sound-treated booth across the test frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz,
- (2) Unmasked automated air-conduction pure-tone testing by the KUDUwave5000 audiometer in a quiet office (ambient noise < 50 dBA) across the frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz, and
- (3) Unmasked self-administered air-conduction pure-tone testing with the ACEScreening device in a quiet office (ambient noise < 50 dBA) across the aforementioned frequencies. Test protocols

employed in each of the experimental conditions were similar to the conventional 10dB down and 5dB up method.

The set of instructions given to each participant differed from one experimental condition to the other. The following sets of instructions were given at the unmasked manual, automated and self-administered air conduction pure tone testing conditions respectively:

“The aim of this test is to identify the softest sounds you can hear. You are going to hear beep tones from this headphone. You will hear many tones in sequence; your duty is to respond by raising your hand anytime you hear the tone, no matter how faint the tone is. Put your hand down anytime you do not hear a tone”,

“The aim of this test is to ascertain the softest sounds you can hear. You are going to hear beep tones from this headphone. You will hear many tones in sequence; your duty is to respond by pressing any of the buttons numbered 1 to 4 anytime you hear the tone, no matter how faint the tone is”,

”Put on the earphones properly and adjust the volume with the ‘+’ or ‘-’ button until the pulsed tone is barely audible. Repeat the procedure as much as you can until the volume is just barely audible”.

The test procedure with the GSI 17 Audiometer commenced at 1000 Hz, in the right ear, familiarizing with 40 dB pure-tone pulsed (1 to 2 seconds) test signal and then proceeded to the higher frequencies in octaves, terminating at 500Hz and 250 Hz. There was no re-test at 1000 Hz. Similarly, the KUDUwave5000 commenced at 1000 Hz and then proceeded to the higher frequencies, terminating at 500 Hz and 250 Hz. The right ear was tested initially, familiarizing

participants with a 40 dB pure-tone pulsed test signal. Test tone in the second scenario lasted for about 1 to 2 seconds. Again, there was no re-test at 1000 Hz. Testing with the ACEScreening device started at 250 Hz in the left ear, familiarizing the participants with a 40 dB pure tone (continuous tone) test signal, and then proceeded to the higher frequencies, terminating at 8000Hz. There was no re-test at 1000 Hz. Testing was performed for right and left ears in all three experimental conditions.

Participants were counterbalanced (a type of design in which all possible orders of presenting the variables are included) in the three experimental conditions to curb order effect and fatigue on the outcome of the study. Therefore, unmasked pure-tone air-conduction thresholds were repeatedly measured with the three test methods via the following different orders:

Table 3.1: Order of counterbalancing employed in study design

	Order of Counterbalancing			
First order	Manual testing with GSI 17 audiometer	Automated testing by KUDUwave5000 audiometer	Self-administered testing with ACEScreening device	
Second order	Self-administered testing with ACEScreening device	Manual testing with GSI 17 audiometer	Automated testing by KUDUwave5000 audiometer	
Third order	Automated testing by KUDUwave5000 audiometer	Self-administered testing with ACEScreening device	Manual testing with GSI 17 audiometer	

The first, second and third orders were employed to test 33, 33 and 34 participants respectively.

All 100 participants were tested within 30 days. Each testing method lasted for about 8 minutes,

with an inter-testing duration of about 1 minute. A participant underwent all test batteries in the same day. In addition, participants were engaged with an alerting task (e.g. state 8 female names beginning with the letter “C”) at regular intervals to keep them attentive throughout the experimental process.

The A-weighted scale of the Larson Davis 824 Sound Level Meter was used by an investigator to monitor ambient noise in the quiet office. Measurements on the spectral characteristics of the ambient noise in the quiet office were also made.

3.10 INFECTION CONTROL

To curb cross infection, TDH49 head phones of the GSI 17 audiometer were sanitized with germ-X Sanitizing Wipes at regular intervals (after each participant). Insert ear tips of the KUDUwave5000 audiometer were discarded after testing each participant and the circumaural headphones of the ACEScreening device were also sanitized with germ-X Sanitizing Wipes before and after testing a participant.

3.11 ETHICAL APPROVAL

Ethical approval was granted by the Ethical and Protocol Review Committee of the School of Biomedical and Allied Health Science, College of Health Sciences, University of Ghana. Also, permission and authorization was granted for the study by the director of the Hearing Assessment Centre, KBTH.

3.12 DATA MANAGEMENT PLAN

Data on the auditory status of participants were kept confidential by identifying participants with reference codes. Who owns the data, copyright stuffs

CHAPTER FOUR

ANALYSES OF RESULTS

4.1 INTRODUCTION

The results of the research study are presented in this Chapter. Details of the results include participants' response rate and demographics, spectral characteristics of ambient noise in the quiet office, mean hearing thresholds and threshold differences obtained via the three test methods (Manual hearing testing with the GSI 17 Audiometer, Automated testing with the KUDUwave5000 Audiometer and self-administered hearing testing with the ACEScreening device), and testing of hypotheses. Statistically, the results are presented via descriptive statistics which provided the means and standard deviations of the research variables and inferential statistics which indicated outcomes of the test of significance of the stated hypotheses.

4.2 DEMOGRAPHICS

4.2.1 Response Rate

Out of 112 participants who initially consented to participate in the study, only 100 participants turned up. Hence an 89% response rate was achieved for this study.

4.2.2 Age, Gender, Education and Hearing Status

The results of the demographic characteristics (age, gender, educational) as well as the hearing status of participants are shown in Tables 4.1 and 4.2 respectively. From Table 4.1, the gender distribution of the participants was 45% ($n=45$) males and 55% ($n=55$) females.

Table 4.1: Age, gender, education demographics

Demographic variable	Gender	Frequency	Percent, %
Gender	Male	45	45
	Female	55	55
Age (years)	8-19	7	7
	20-29	69	69
	30-39	14	14
	40-49	1	1
	50-59	4	4
	60-69	4	4
	70-79	2	2
Education	Basic/Vocational	10	10
	Secondary	15	15
	Tertiary	75	75

Table 4.2: Hearing status of participants

Hearing status	Frequency	Percent, %
Normal hearing	152	76.0
Conductive hearing loss	22	11.0
Sensorineural hearing loss	16	8.0
Mixed hearing loss	10	5.0
Total number of ears	200	100

The ages of participants ranged from 8 to 79 years with mean of 28 ± 10.43 years. The most prevalent year group was 20-29 years ($n=69$, 69%) while 40-49 and 70-79 years groups presented the prevalence of 1% ($n=1$) and 2% ($n=2$) respectively. With respect to education, 75%

($n=75$) out of the population had obtained tertiary level education, whereas the secondary and basic/vocational levels recorded relatively lower rates of 15% ($n=15$) and 10% ($n=10$) respectively. Among the ears tested, 152 (76%) had normal hearing. The prevalence of the other hearing status were conductive hearing loss ($n= 22$ ears, 11%); sensorineural ($n=16$ ears, 8%); and mixed hearing loss (10 ears, 5%).

4.3 SPECTRAL CHARACTERISTICS OF AMBIENT NOISE IN THE QUIET

Ambient noise measurements were conducted in the quiet office which was used as one of the test laboratories. Spectral characteristics of the measured ambient noise were determined across the entire frequency test range. The results are shown in Figs 4.1- 4.4.

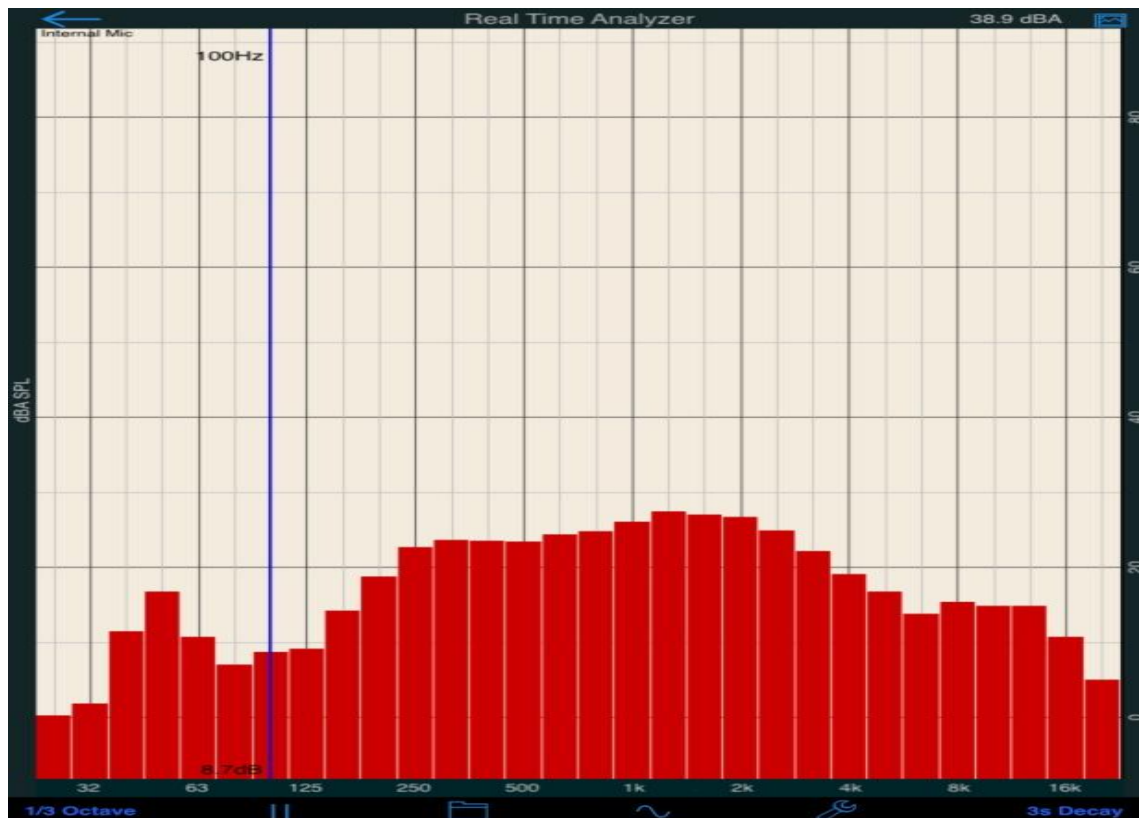


Fig. 4.1: Sample of the spectral characteristics of ambient noise in the quiet office (38.9dBA)



Fig. 4.2: Sample of the spectral characteristics of ambient noise in the quiet office (39.1dBA)

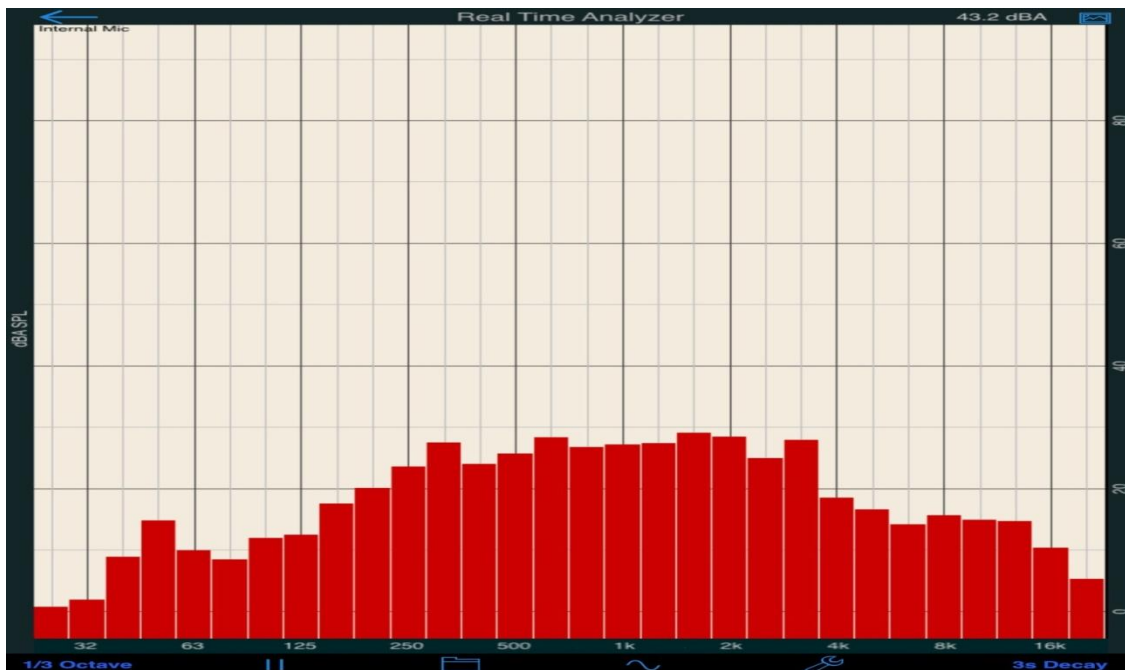


Fig. 4.3: Sample of the spectral characteristics of ambient noise in the quiet office (43.2dBA)

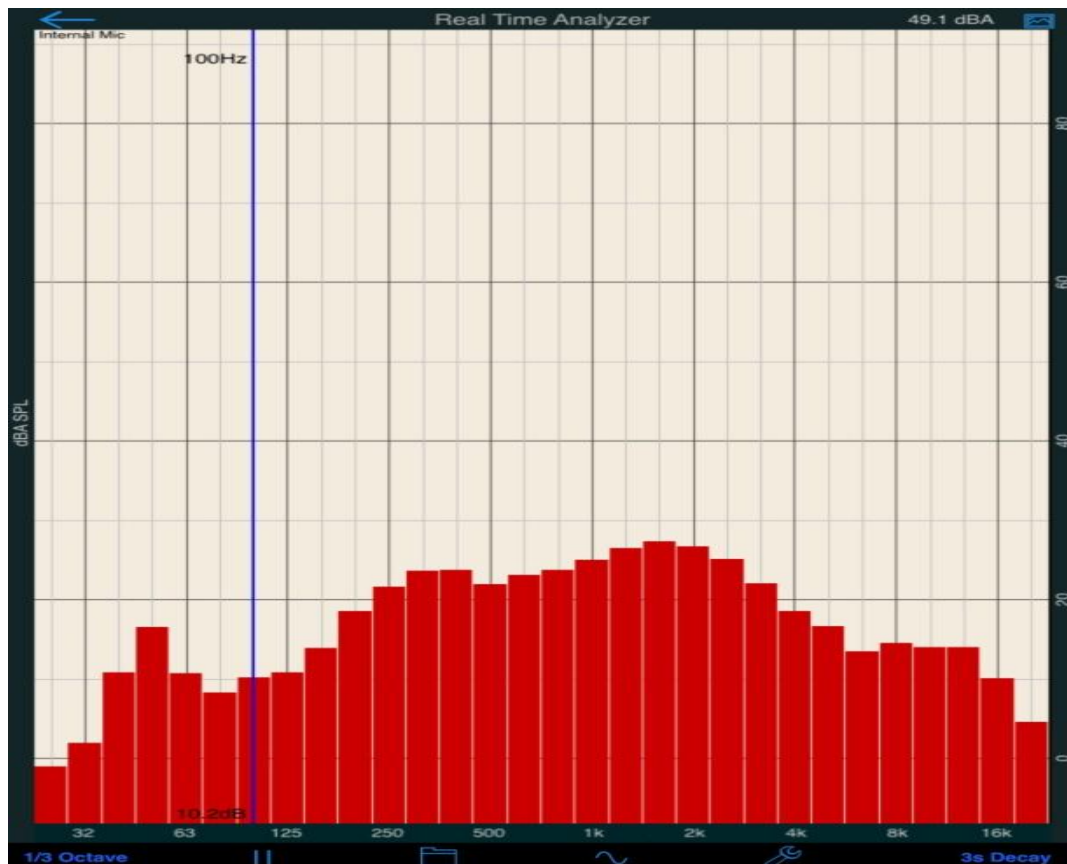


Fig. 4.4: Sample of the spectral characteristics of ambient noise in the quiet office (49.1dBA)

The spectral characteristics showed that the sound intensities were more prominent at lower frequencies (250Hz, 500Hz, 1000Hz and 2000 Hz) than at higher frequencies (4000Hz and 8000 Hz). The average ambient noise was 47.2 dBA.

4.4 MEASURED HEARING THRESHOLDS AND THRESHOLD DIFFERENCE

4.4.1 Mean Thresholds and Threshold Difference at Test Frequencies and Ear via Test

Methods

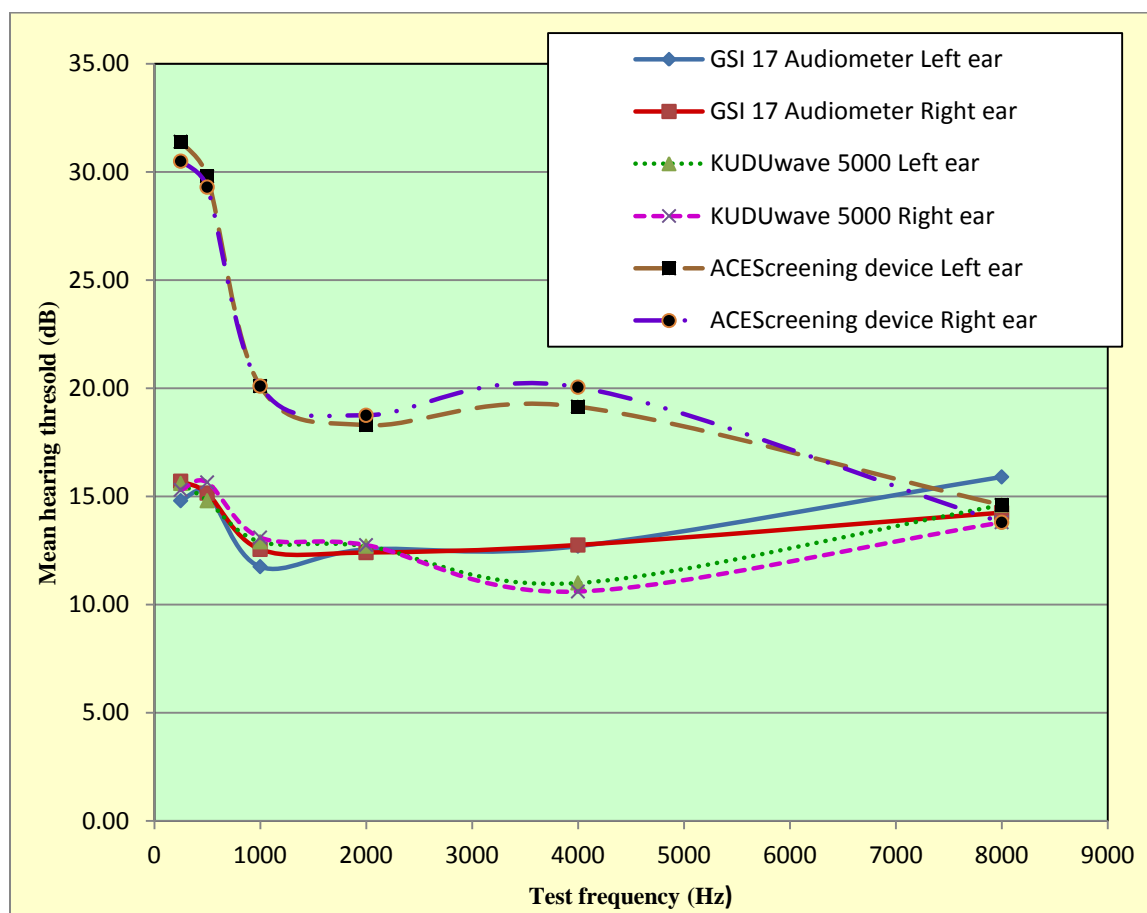
The descriptive statistics of unmasked pure tone air-conduction hearing thresholds and threshold differences measured via the three test methods at the defined test frequencies for both right and left ears are depicted in Tables 4.3, 4.4 and Fig. 4.1.

Table 4.3: Mean thresholds at test frequencies and ear via test methods

Testing methods	Hearing threshold (mean \pm s.d) dB						
	GSI 17 audiometer		KUDUwave5000 audiometer		ACEScreening device		
	Right ear	Left ear	Right ear	Left ear	Right ear	Left ear	
Frequency (Hz)	250	15.70 \pm 10.35	14.80 \pm 9.15	15.30 \pm 10.20	15.60 \pm 12.07	30.50 \pm 7.60	31.40 \pm 8.04
	500	15.15 \pm 9.31	15.15 \pm 8.57	15.65 \pm 10.10	14.80 \pm 10.10	29.30 \pm 7.35	29.80 \pm 8.01
	1000	12.55 \pm 9.78	11.75 \pm 9.78	13.10 \pm 10.44	12.90 \pm 10.47	20.10 \pm 7.49	20.10 \pm 7.21
	2000	12.40 \pm 12.26	12.55 \pm 11.60	12.75 \pm 12.02	12.70 \pm 11.04	18.75 \pm 8.60	18.30 \pm 7.36
	4000	12.75 \pm 13.81	12.70 \pm 13.57	10.60 \pm 13.09	11.00 \pm 12.69	20.05 \pm 10.77	19.15 \pm 10.35
	8000	14.25 \pm 14.55	15.90 \pm 15.10	13.80 \pm 14.25	14.60 \pm 14.90	19.50 \pm 10.70	19.40 \pm 10.48

Table 4.4: Mean threshold differences at test frequencies and ear via test methods

Frequency (Hz)	Mean threshold differences (dB)			
	GSI 17 vrs KUDUwave 5000		GSI 17 vrs ACEScreening	
	Right ear	Left ear	Right ear	Left ear
250	0.4	-0.8	-14.8	-16.6
500	-0.5	0.4	-14.2	-14.7
1000	-0.6	-1.2	-7.40	-8.40
2000	-0.35	-0.15	-6.40	-5.80
4000	2.15	1.70	-7.30	-6.50
8000	0.45	1.30	-5.30	-3.50

**Fig. 4.5: Mean thresholds for GSI 17, KUDUwave 5000 and ACEScreening systems**

The results show that the mean air-conduction hearing threshold difference between the GSI 17 audiometer and the KUDUwave5000 audiometer across each test frequency for both right and left ears was less than 5 dB. Also, the mean air-conduction hearing threshold differences between the GSI 17 Audiometer and the ACEScreening device was less than 17 dB for low frequencies (250Hz - 500 Hz) and less than 10dB at higher frequencies (1000Hz - 8000 Hz).

4.7 TEST OF HYPOTHESES

The Pearson-Moment r correlation test was employed to test the earlier defined hypotheses for the study. The results of the study conducted on both ears are displayed in Table 4.5.

Correlation values of $r = 0.71, 0.82, 0.92, 0.93, 0.90, 0.93$ and $r=0.66, 0.82, 0.88, 0.89, 0.92, 0.95$ were computed for right and left ears respectively, with $p < 0.05$. These statistics clearly established that a significant strong positive correlation existed between the unmasked pure tone air-conduction thresholds obtained by the KUDUwave5000 Audiometer in a quiet office and the GSI 17 audiometer in a sound-treated booth across the test frequency range for right and left ears. Hence, the first stated hypothesis was not supported by the study data.

Table 5: Pearson-Moment r correlation test on thresholds obtained via test methods

		GSI 17 audiometer					
Screening device		Test frequencies (Hz)					
Frequency	Ear	250	500	1000	2000	4000	8000
		KUDUwave5000 audiometer					
250	Right	0.71*					
	Left	0.66*					
500	Right		0.82*				
	Left		0.82*				
1000	Right			0.92*			
	Left			0.88*			
2000	Right				0.93*		
	Left				0.89*		
4000	Right					0.90*	
	Left					0.92*	
8000	Right						0.93*
	Left						0.95*
		ACEScreening device					
250	Right	0.57*					
	Left	0.48*					
500	Right		0.53*				
	Left		0.56*				
1000	Right			0.68*			
	Left			0.63*			
2000	Right				0.86*		
	Left				0.82*		
4000	Right					0.87*	
	Left					0.86*	
8000	Right						0.86*
	Left						0.86*

Note: * $p < 0.05$

Additionally, there was a moderate (250Hz-500Hz) to strong (1kHz-8kHz) positive significant correlation between the unmasked pure tone air-conduction thresholds obtained with the ACEScreening device and the GSI 17 audiometer under the same conditions described above across the same frequencies for right and left ears. The estimated correlation coefficients were r

= 0.57, .053, 0.68, 0.85, 0.87, 0.86 and $r = 0.48, 0.56, 0.63, 0.82, 0.86, 0.86$ for right and left ears respectively with $p < 0.05$. Therefore, the second hypothesis was not also supported by the data collected.

4.8 SUMMARY OF RESULTS

The descriptive and inferential statistics revealed that:

- (1) There was a significant strong positive correlation between the unmasked pure tone air-conduction thresholds obtained by the KUDUwave5000 audiometer in a quiet office and the same experiment obtained with the GSI 17 audiometer in a sound-treated booth across the test frequency range for right and left ears.

The mean differences revealed that the mean air-conduction hearing threshold difference between the GSI 17 audiometer and the KUDUwave5000 audiometer across each tested frequency for both right and left ears was less than 5 dB

- (2) Under the same test conditions described above, a significant moderate to strong positive correlation between the unmasked pure tone air-conduction thresholds obtained with the ACEScreening device and the GSI 17 audiometer in a sound-treated booth across all the frequency range for right and left ears was established.

The mean air-conduction hearing threshold differences between the GSI 17 audiometer and the ACEScreening device was less than 17 dB at 250 and 500 Hz and less than 10dB at 1000, 2000, 4000 and 8000 Hz.

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 INTRODUCTION

The study investigated the validity of the ACEScreening device as a self-administered hearing screening test and the KUDUwave5000 audiometer as an automated diagnostic audiometer. In view of this, two hypotheses were set and tested. The results revealed a significant strong positive correlation between the unmasked pure-tone air-conduction thresholds obtained with the GSI 17 audiometer in a sound-treated booth and those obtained by the KUDUwave5000 audiometer and a significant moderate to strong positive correlation between the GSI 17 audiometer in a sound-treated booth and ACEScreening device in a quiet office across the defined test frequencies of 250Hz, 500Hz, 1 kHz, 2kHz, 4kHz and 8 kHz for right and left ears.

Further analysis showed that the mean air-conduction hearing threshold difference between the reference GSI 17 audiometer and the KUDUwave5000 audiometer across each tested frequency for both right and left ears was less than 5dB. The mean air-conduction hearing threshold differences between the GSI 17 audiometer and the ACEScreening device was less than 17 dB at 250 and 500 Hz and less than 10dB at higher frequencies from 1 kHz to 8 kHz.

5.2 EFFECT OF ORDER AND FATIGUE ON HEARING THRESHOLDS

Participants were counterbalanced in the three experimental conditions to curb order effect and fatigue on the outcome of the study. Order effect was apparent due to learning, yielding a better response to pure-tone test signals. Thus, hearing thresholds improved after initial experimental conditions. Fatigue affected the reliability of hearing thresholds to an extent. However, the effect

of order and fatigue on the outcome of the study was not significant due to the introduction of counterbalancing in the experimental design.

5.3 THE GSI 17 AUDIOMETER AND THE KUDUwave5000 AUDIOMETER

The first hypothesis which stated that there will be a significant strong negative correlation between the unmasked pure tone air-conduction thresholds obtained by the KUDUwave5000 Audiometer in a quiet office and the same experiment obtained with the GSI 17 Audiometer in a sound-treated booth (gold standard) across the frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz for right and left ears was not supported by the data collected. This is indicative that the unmasked pure tone air-conduction thresholds of the KUDUwave5000 increased with corresponding increases in the unmasked pure tone air-conduction thresholds of the GSI 17 audiometer and vice versa. Subsequent analysis showed that the mean unmasked pure tone air-conduction hearing threshold difference between the reference GSI 17 audiometer and the KUDUwave5000 audiometer across each tested frequency for both right and left ears was less than 5dB. This difference is within the acceptable standard for manual air conduction threshold variability. The finding is consistent with studies by Mahomed, et al (2013); Swanepoel, et al (2013); Margolis, et al (2010); Margolis & Moore (2011); Margolis, et al (2011); Henry, et al (2001); Foulad, et al (2013); Convey, et al (2014) who purported that the air-conduction hearing threshold variability between the conventional manual and automated audiometry were within acceptable limits.

The current finding can be explained by the fact that the insert ear phones and circumaural audiocups of the KUDUwave5000 audiometer provided a standard environmental condition for pure-tone testing by attenuating the ambient noise to an acceptable limit. Hence masking of test

signals that leads to significant threshold shifts were controlled. In conclusion, the results from this study suggest that the KUDUwave5000 audiometer may be used in conducting unmasked air-conduction hearing testing in a quiet environment where the ambient noise is higher than the maximum permissible ambient noise levels

5.3 THE GSI 17 AUDIOMETER AND THE ACEScreening DEVICE

The second hypothesis which stated that there will be a significant strong negative correlation between the unmasked pure tone air-conduction thresholds obtained with the ACEScreening device in a quiet office and the same experiment obtained with the GSI 17 audiometer in a sound-treated booth (gold standard) across the frequencies of 250, 500, 1000, 2000, 4000 and 8000 Hz for right and left ears was not also supported by the data collected. This means that the unmasked pure tone air-conduction thresholds of ACEScreening device increased with increases in the unmasked pure tone air-conduction thresholds of the GSI 17 audiometer and vice versa.

Further analysis of the mean thresholds revealed that the mean air-conduction hearing threshold differences between the GSI 17 audiometer and the ACEScreening device was more than 10dB at 250 and 500 Hz but less than 10dB at 1 kHz to 8 kHz. The unmasked pure tone air conduction threshold mean differences at 250 and 500 Hz (14.8 and 16.6 dB for right and left ears respectively) were relatively higher. This was evidenced in the respective correlation coefficients. This result can be attributed to two main reasons

- The utilization of a non-clinical transducer in conducting unmasked air conduction pure tone testing for the ACEScreening Device
- Spectral characteristics of the ambient noise in the quiet office and sensitivity of human ear as a function of frequency

5.3.1 Significance of the Non-Clinical Transducer (Senheisser HDA 205)

Krumm (2010) considered that ambient noise must be abated either via environmental or headphone solutions in conducting pure tone testing with computerized audiometers. However, there is no specified standard for calibrating non clinical headphones used in pure tone audiometry. The lack of specific standards in calibration could have affected the output of the Senheisser HDA 205 noise-cancelling headphone, especially in the case of comparison with the output of a clinical headphone. In particular, variations in the headband tension of a clinical headphone compared to a non-clinical headphone can lead to significant differences in output thresholds. This condition could have contributed to the relative increase in the unmasked pure tone air-conduction mean differences at 250 and 500 Hz.

5.3.2 Spectral Characteristics of Ambient Noise and Sensitivity of the Human Ear

The spectral characteristics of ambient noise in the quiet office depicted that the sound intensities were more prominent in the 25 kHz – 2 kHz range than at 4 kHz and 8 kHz. However there were more significant shifts of unmasked pure tone air conduction hearing thresholds at 250 and 500 Hz than in the 1 kHz – 8 kHz band. This is because the human ear is more sensitive to sounds from 1 kHz – 4 kHz than at 250Hz and 500 Hz. This variability in sound perception at different frequencies partly accounts for improvements in loudness perception of some pure tones (1 kHz – 4 kHz) in the presence of a fairly constant ambient noise spectrum. The noise spectra also showed relatively minimal noise intensities at 8 kHz. This could account for the least significant threshold shift at this frequency. Hence, despite the spectral characteristics of the ambient noise, the mean unmasked air conduction hearing threshold differences were relatively better at 1 kHz- 8 kHz (less than 10 dB) than at 250 and 500 Hz (greater than 10dB). The current finding is consistent with studies by Yu, et al (2011) and Louise, et al (2010) who purported that the air-

conduction hearing threshold variability between the conventional manual and self-administered audiometry where within acceptable limits.

In conclusion, it is tenable that the ACEScreening device can be used as a screening device to conduct unmasked pure tone air conduction hearing test in a quiet office where the ambient noise is a little higher than the maximum permissible ambient noise levels for audiometric test environment.

CHAPTER SIX

CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

6.1 INTRODUCTION

This Chapter includes conclusions drawn from the outcome of the results, recommendations for future research consideration, policy implementations and hearing health technological development and the limitations of the study.

6.2 CONCLUSION

Based on the findings of the study, the KUDUwave5000 audiometer may be used to conduct an unmasked air-conduction hearing test in a quiet environment where the ambient noise is higher than the maximum permissible ambient noise levels. On the other hand, the ACEScreening device can be used to conduct unmasked air conduction hearing test in a quiet environment as a screening device where the ambient noise is a little higher than the maximum permissible ambient noise levels.

6.3 RECOMMENDATIONS

On the bases of the findings in this study, the following recommendations are made for future research consideration and policy implementations:

- (1) Test-retest reliability measurements should be performed as part of the experiment in subsequent researches.
- (2) Hearing screening and ototoxicity monitoring with the ACEScreening device should be conducted from 500 to 8000 Hz

- (3) It is also recommended that future studies focus on the validity of computerized bone conduction audiometry in the natural environment, validity of automated and self-administered audiometry among difficult-to-test populations etc.
- (4) In addition, it is recommended to policy makers in government and non-governmental institutions in charge of education and health, such as the Ghana Education Service, the Ministry of Education, the Ghana Health Service and the Ministry of Health to adopt these computerized devices into the application of telemedicine to extend hearing healthcare services to underserved communities.
- (5) Future studies should also focus on the utilization of insert earphones in conducting self-administered hearing test with mobile phone applications in the natural environment

6.4 LIMITATIONS OF THE STUDY

The major limitations of this study were time constraints. Due to this challenge, test re-test reliability of the three test methods could not be performed. Again, the population of the study had to be increased to enable more participants to be recruited in order to meet the deadline for the study.

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APPENDICES**PARTICIPANTS INFORMATION SHEET****VALIDITY OF COMPUTERIZED AUDIOMETERS: A CASE INVOLVING THE
KUDUwave 5000 AND THE ACEScreening DEVICE**

You are invited to join a research study to look at the validity of computerized audiometers. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you.

If you decide to participate, you will be asked to join. This will take you about 15 minutes. You can stop the study at any time. If you stop, you will not lose any benefits. The techniques applied in this study are non-invasive and involves no risk. You are guaranteed of the benefit of knowing your hearing status after completing the various tests.

All the necessary steps will be taken to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage.

Call Ronald Nkansah Adjekum on 0543959049 or email ronaldadjekum@yahoo.com if you have questions about the study or any problems Thank you

Ronald Nkansah Adjekum,

Department of Audiology, UG.

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Head Of Department

Department of Audiology

.....

DATA MANAGEMENT FORM**PATIENT'S REFERENCE CODE:****DATE:****AGE:****TIME****GENDER:****AMBIENT NOISE MEASUREMENT:****TYPE OF HEARING LOSS (a) Conductive (b) Sensorineural (c) Mixed****EDUCATIONAL LEVEL (a) Basic (b) Secondary (c) Tertiary****HEARING THRESHOLDS FOR RIGHT EAR**

FREQUENCY (Hz)/ INTENSITY (dBHL)	250	500	1000	2000	4000	8000
GSI 17 Audiometer						
KUDUwave5000						
ACEScreening Device						

HEARING THRESHOLDS FOR LEFT EAR

FREQUENCY (Hz)/ INTENSITY (dBHL)	250	500	1000	2000	4000	8000
GSI 17 Audiometer						
KUDUwave5000						
ACEScreening Device						

**SCHOOL OF ALLIED HEALTH SCIENCES
COLLEGE OF HEALTH SCIENCES
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**My Ref. No. SAHS/ 10251549
Your Ref. No.**



P. O .Box KB 143
Korle Bu
Accra
Ghana

12th May, 2014.

Mr. Ronald Nkansah Adjekum,
Dept. of Audiology,
SAHS,
Korle Bu.

Dear Mr. Adjekum,

ETHICS CLEARANCE

Ethics Identification Number: SAHS – ET. /10251549/AA/1A/2013-2014.

Following a meeting of the Ethics and Protocol Review Committee of the School of Allied Health Sciences held on Monday 24th March, 2014, I write on behalf of the Committee to approve your research proposal as follows:

TITLE OF RESEARCH PROPOSAL: "Validity Assessment of Computerized Audiometry: A Case Involving the KUDUWave5000 and the ACEScreening Device"

This approval requires that you submit six-monthly review reports of the protocol to the Committee and a final full review to the Committee on completion of the research. The Committee may observe the procedures and records of the research during and after implementation.

Please note that any significant modification of the research must be submitted to the Committee for review and approval before its implementation.

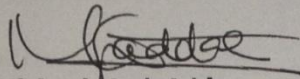
You are required to report all serious adverse events related to this research to the Committee within seven (7) days verbally and fourteen (14) days in writing.

As part of the review process, it is the Committee's duty to review the ethical aspects of any manuscript that may be produced from this research. You will therefore, be required to furnish the Committee with any manuscript for publication.

Please always quote the ethical identification number in all future correspondence in relation to this protocol.

Thank you.

Yours sincerely,



Dr. Michael Mark Addae
(Chairman, Ethics and Protocol Review Committee)

cc Dean
 Co-ordinator/HoD, Dept. of Audiology
 Senior Assistant Registrar

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P O Box KB 143,
Korle Bu

My Ref. No. SAHS/

Your Ref. No.

August 20, 2013

The Head
Hearing Assessment Centre
Korle Bu Teaching Hospital

Dear Sir,

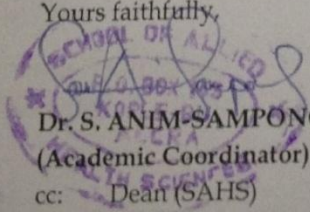
PERMISSION TO CARRY MSc RESEARCH PROJECT AT THE HEARING
ASSESSMENT CENTRE, KORLE BU TEACHING HOSPITAL

Mr. Ronald N. Adjekum is a 2nd year MSc Audiology student in the Department of Audiology of the University of Ghana School of Allied Health Sciences (SAHS).

He is conducting a MSc research project on validity of a computerized self-administered screening device at the Hearing Assessment Centre of KBTH under the supervision of Dr. S. Anim-Sampong (SAHS) and Prof. G.K. Amedofu (KBTH/KATH).

The Department would be most grateful if you could kindly grant him permission to carry out this important research project from August - March 2013 for the common good of the University and the hospital. Thank you.

Yours faithfully,


Dr. S. ANIM-SAMPONG
(Academic Coordinator)

cc: Dean (SAHS)

HEARING ASSESSMENT CENTRE

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No.....

Your Ref. No.....



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28th October, 2013

The Academic Coordinator
Department of Audiology
School of Allied Health
College of Health Sciences
University of Ghana

Dear Sir,

**RE: PERMISSION TO CARRY OUT MSc RESEARCH PROJECT AT THE
HEARING ASSESSMENT CENTRE, KORLE BU TEACHING HOSPITAL**

Mr. Ronald N. Adjekum has been granted permission to conduct an MSc research project on the validity of a computerized self-administered screening device at the Hearing Assessment Centre.

It is recommended that he presents and demonstrates the screening device as well as any questionnaires to be administered to the in charge of the Centre prior to the commencement of data collection.

Thank you.

Yours sincerely,

Jemima Fynn (Mrs.)
Audiologist in Charge

