DEVELOPING CLINICAL NORMATIVE DATA FOR NEONATES USING AUDITORY BRAINSTEM RESPONSE AT KORLE BU TEACHING HOSPITAL

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DECLARATION

I **FRANKLIN AKUAMOAH**, do hereby declare that this thesis which is being submitted in fulfillment of the requirements for the Masters degree (MSc) in Audiology is the result of my own research performed under supervision, and that except where otherwise other sources which 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 research work is dedicated to the Holy Spirit, my true friend, source of my knowledge, wisdom and encouragement. This work is dedicated to my kids Eunice Akuamoah, Divine Akuamoah and Aaron Akuamoah. It is also dedicated to Fafali Esi Dziedzoave Akuamoah and Theodora Akuamoah Agyepong

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ABR	Auditory Brainstem Response
AEPs	Auditory Evoked Potentials
KBTH	Korle – Bu Teaching Hospital
HAC	Hearing Assessment Centre
HIS	Intelligent Hearing System
CNS	Central Nervous System
IPL	Inter-Peak Latency
TOAE	Transient Otoacoustic Emission
NHS	Newborn Hearing Screening
EP	Evoked Potentials

ABSTRACT

Background: Undetected hearing loss in neonates and children compromises optimal speech and language development and personal achievement. Auditory brainstem response (ABR) test consists of eliciting and recording waveforms generated within the auditory nerve region to the brainstem. These waveforms are compared with normative data to determine normal and abnormal responses. The use of ABR in identifying, and managing infants with congenital hearing impairment is crucial to their academic, social and personal wellbeing.

Aim: The aim of the study was to develop an ABR clinical normative data for neonates within the age bracket of 2 to 8 weeks to ensure objective and valid interpretation of test results.

Methods: A prospective study design was used to develop clinical normative data from 30 normal hearing neonates within the age bracket of 2 to 8 weeks. The ABR tests were performed using the smart EP equipment in an acoustically treated room. The ER 3A insert earphones were used, and recordings of responses were made using surface electrodes (disposable), positioned according to the international 10-20 system (Cz: front; A1: right lobe, and A2: left lobes), adapting the impedance below 3 kΩ. All examinations were performed with the babies in natural sleep. A presentation level of 80 to 30 dBHL in 10 dB decrements was utilized.

Results: The results of the study revealed that the absolute and inter-peak mean latencies for the normative data established by the present study were within 2 standard deviations of the published data. The present study showed statistically significant effects of gender on mean absolute latencies for wave V at 30, 40, 50 and 60 dBnHL and also on inter-peak I-III at 70 dBnHL. However, there was no significant effect of gender on other absolute and inter-peak mean latencies.

Conclusion: The study concluded that the developed normative data was appropriate and useful for ABR testing and recommended the need for further investigations to be conducted on the effect of gender on neonatal ABR latencies.

Keywords: Auditory Brainstem Response, Neonates, Latency, Inter-peal Latency, Evoked Potential

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Hearing impairment in children across the globe poses hindrance to their optimal speech and language development. The socio-economic, academic and psychological impact of hearing impairment affects the wellbeing of such children and their families. Studies have shown that, bilateral permanent childhood hearing impairment ranging from moderate to severe hearing loss can lead to major deficiencies in the development of language (Tanon-Anoh, Sanogo-Gone and Kouassi, 2010). According to Olusanya, Emokpae and Renner (2009), 278 million people globally have moderate to profound hearing impairment, out of which 68 million originated from childhood.

Annually, 798,000 babies worldwide suffer from permanent hearing loss at birth or within the neonatal period (Olusanya et. al., 2009). Meyer and Swanepoel (2011) reported that, approximately 180, 000 babies are born yearly with permanent bilateral hearing loss within the first few weeks of life across Sub-Saharan Africa. While an estimated number of 17 babies presenting with varying degree of hearing impairment are born with a significant permanent bilateral hearing loss every day in South Africa. These neonates can be identified early if systematic newborn and infant hearing screening programmes are implemented (Meyer and Swanepoel, 2011).

Jacobson and Hall (1994) proposed that, the current limitations associated with conventional behavioral audiometry in neonates and very young infants require the use of objective measures

to ensure valid estimates of auditory sensitivity. The use of auditory evoked potentials (AEPs) such as auditory brainstem response (ABR) represents an acceptable clinical technique and an essential tool for assessment of hearing loss in pediatric populations (Jacobson and Hall, 1994). Rosa, Suzuki, Angrisani and Azevedo (2014) defined ABR as a set of electrical responses generated at various anatomical sites (within the auditory nerve and lower brainstem) after auditory stimulus presentation.

According to Ness (2009), ABR consists of seven recognizable waveforms labeled with Roman numerals (I-VII). Clinically, an ABR is analyzed in terms of waveforms I, III and V which occur within 10 ms after presentation of auditory stimulus. The waveforms elicited during an ABR can be used to determine normal versus abnormal responses when compared with normative data. Ness (2009) noted that, ABR is very useful in clinical audiology. First, the ABR can be used to detect retrocochlear pathologies of the auditory system, such as vestibular schwannomas that originate in the internal auditory meatus, auditory neuropathy and multiple sclerosis that affect the anatomical structures located above the level of the cochlea. Additionally, ABR can be used as a clinical measure to assess the integrity of the auditory function from the peripheral auditory system to the level of the lower brainstem (Ness, 2009). Jacobson and Hall (1994) purported that, ABR test results can be interpreted and applied with clinical confidence based on the establishment of normative data as a bench mark. Consequently, Shivaji et al. (2013) noted that, ABR is a useful test for estimating hearing loss, especially in difficult-to-test populations such as premature babies, children with delayed milestones, attention deficit and other sensory or motor impairments who cannot complete a traditional behavioural audiological evaluation. Although ABR has become the objective test of choice for paediatric auditory assessment, inter laboratory

differences have had a major limitation on the application of normative values in the interpretation of test results. (Chalak, Kale, Deshpande, & Biswas, 2013).

In Ghana, there is limited data on the prevalence of hearing loss among neonates. To minimize the impact of hearing loss in children, early identification of hearing loss, appropriate diagnosis and early intervention is crucial (Amedofu, Ocansey and Antwi, 2006).

1.2 PROBLEM STATEMENT

Undetected hearing loss in neonates and children compromises optimal speech and language development and personal achievement. Delays in acquisition of language and communication affect literacy, academic achievement, social and personal development (Olusanya, Luxon and Wirz, 2004). In addition, the society is burdened with the extensive economic costs associated with individuals with hearing impairment. Hearing loss without adequate intervention affects an individual's ability to obtain, perform and keep a job.

Hearing loss also causes isolation and stigmatization of people (Health Professional Council of South Africa, 2007). The application of appropriate measures such as ABR in identifying, and managing neonates with congenital hearing impairment is crucial to their academic, social and personal wellbeing (Jacobson and Hall, 1994). According to Hood (1998), ABR consists of eliciting and recording waveforms generated within the auditory nerve region to the lower brainstem. These waveforms are compared to normative data to determine normal and abnormal responses. Jacobson and Hall (1994) reported that, differences in instrumentation and recording parameters (inter-laboratory differences) requires each audiology clinical facility to develop its own set of ABR norms. The on-going ABR testing for neonates at Korle Bu Teaching Hospital

(KBTH) Hearing Assessment Centre uses the published clinical normative data for waveforms interpretation. This may not appropriately serve Ghanaian neonate population due to inter-laboratory differences (Chalak, Kale, Deshpande, & Biswas, 2013).

There is the likelihood that inter-laboratory differences such as testing environment, tester and protocol setting may result in differences between the clinically developed normative data and the published data. This could lead to discrepancies in interpretation of waveforms that may result in wrongful identification and reporting of neonatal hearing loss. Therefore, to ensure objective and valid interpretation of auditory sensitivity of neonates in KBTH, it is important to establish a clinical normative data for neonate ABR testing.

1.3 SIGNIFICANCE OF THE STUDY

The normative data established by this study will be significant in the following ways:

1. To serve as a gold standard for comparing wave latencies and inter-wave latencies for early identification of neonates with hearing difficulties within Ghana.
2. To determine the integrity of auditory function of neonates from the peripheral auditory system to the level of the lower brainstem.

1.4 HYPOTHESES

The study was guided by the following types of hypotheses:

H_1: There will be no significant clinical difference between the clinically developed normative values and the IHS published normative values for waves I, III, V and inter-peak I-III, III-V and I-V latencies.

H_2: Gender will have no significant effect on absolute and inter-peak mean latencies at all tested intensities

1.5 AIM OF THE STUDY

The aim of the study was to develop clinical normative data for neonates using ABR. This would ensure objective and valid interpretation of ABR test results of neonates at KBTH.

1.6 OBJECTIVES OF THE STUDY

The specific objectives of this research were to:

1. develop normative data for waves I, III, V and inter-peak I-III, I-V, III-V in the Hearing Assessment Centre of KBTH for neonates within the age bracket of 2 to 8 weeks.
2. compare the clinically developed normative data for neonates within the age bracket of 2 to 8 weeks with the IHS published normative values for the same age bracket.
3. determine gender effect on the developed absolute and inter-peak latency values.

1.7 DEFINITION OF TERMS

Latency: Time taken for the response (waves) to occur after sound is presented to the auditory system

Inter-peak latency (IPL): The time interval between peaks

Neonates: Babies with the age range of 2 to 8 weeks

Evoked potentials: Electrical responses of the nervous system that are elicited by a stimulus.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

This Chapter reviews related literature of earlier studies conducted on ABR and sourced from research articles, journals, books on ABR and normative data for ABR. The areas reviewed included generators of ABR, anatomy of the auditory pathway, test parameters factors that affect ABR results, noise, studies on developing normative data and clinical applications of ABR.

2.2 AUDITORY BRAINSTEM RESPONSE

Three types of responses can be elicited, including middle and late responses in respect of latencies, of which the brainstem response constitutes the first part (Alwan, 2012).

Evoked potentials are electrical responses that occur within the lower brainstem when the nervous system is stimulated and recorded by placing electrodes behind the right or left earlobe and at the high forehead. The changes in the electrical responses or signals are picked up by the electrodes (Gelfand, 2009; Alwan, 2012). Evoked potentials of the auditory system are obtained from the auditory nerve to the auditory cortex of the lower brainstem in response to sound presented to the auditory system.

Auditory brainstem response is a component of the auditory evoked potential that occurs in the first 10 milliseconds after stimulus presentation to the ear at high intensities (Alwan, 2012). These potentials represent electrical activities originating in the afferent auditory pathway during

its course from the inner ear to the brain. Sohmer and Feinmesser (1965) recorded cochlear responses and full ABR responses from the scalp on animals. However, it was first reported in humans by Jewett, Romano and Willinston (1970) who later published their findings on animal and human scalps (Jewett, 1970; Jewett et al., 1980).

2.3 GENERATORS OF AUDITORY BRAINSTEM RESPONSE WAVEFORM

The exact anatomical structures which generate the ABR peaks are still debatable (Moeller, 2007). One complicating factor is the relatively distant measurement point of the ABR on the scalp of the subject. Electrical potentials generated by the auditory neural system are extremely small (approximately 20μV to 40μV for a single neuron) and are not detectable at the scalp unless many nerve fibers fire simultaneously and are aligned such that the potentials flow in the same direction (Eggermont, 2007). Also, the tissues through which the electrical activity must flow affect how well they are measured at the scalp. For example, the petrous portion of the temporal bone is among the densest bone in the body and therefore offers high resistance to electrical flow. Conversely, intracranial fluid and perilymph offer low resistance and thus are more conducive to allowing electrical potentials to flow towards the scalp from the auditory system (Eggermont, 2007). These factors complicate identifying specific generator sites for the electrical potentials of the auditory system that are measured during an ABR.

Despite these difficulties, many studies have agreed on possible sources for the waveforms of the ABR (Ness, 2009). The anatomical origins of the ABR, often labeled with Roman numerals (I-VII), have been demonstrated in both animals and human subjects (Jewett, 1970). In particular, Hall (2007) reported that, waveform I is generated from cranial nerve eight (auditory nerve) and

represents the action potential of the acoustic nerve and arises from the distal portion of cranial nerve eight within the inner ear. The response originates from activities of the auditory nerve fibres as they exit the cochlea into the internal auditory canal (Hall, 2007).

The ABR wave II and III are generated by neurons in the cochlear nucleus and superior olivary complex respectively (Hood, 1998), while waveforms IV and V originate from the lateral lemniscus and neurons in the inferior colliculus and the fiber tracts connecting them on the contralateral side of stimulation respectively (Ness, 2009). The ABR wave VI and VII are generated from the medial geniculate body and auditory cortex. Only three prominent wave components (waves I, III, and V) are typically discernable in newborns at high click intensity presentation levels compared to five to seven wave peaks that are observable in adults.

Table 2.1: Generators of ABR Wave Forms

Waveform	Generators
Wave I	Cochlear nerve (nerve eight)
Wave II	Cochlear nucleus
Wave III	Superior olivary complex
Wave IV	Nucleus of lateral lemniscus
Wave V	Inferior colliculus
Wave VI	Medial geniculate body
Wave VII	Auditory cortex

Source: (AlRouq, 2012).

2.4 ANATOMY OF THE AUDITORY PATHWAY

The human auditory pathway consists of two major components that work in unison to transmit and analyse auditory stimuli. These are: the peripheral and central auditory components.

2.4.1 Peripheral Auditory Pathway

This pathway consists of the outer, middle and inner ear. The outer ear comprises of the pinna, external auditory meatus and the tympanic membrane (Lambell, 2013). The pinna functions as a funnel for collecting sound waves transmits it into the auditory canal and conveys the sound waves towards the tympanic membrane. The middle ear on the other hand is an air-filled chamber located behind the tympanic membrane. It has three small bones namely: malleus, incus and stapes. When sound waves come in contact with the tympanic membrane, it causes the bones to vibrate. This helps in carrying signals to the inner ear that consist primarily of the cochlea and vestibular apparatus (Lambell, 2013). The cochlea is a fluid-filled structure that converts mechanical signals into nerve impulses.

When the stapes in the middle ear strikes the oval window, it creates waves in the inner fluid of the cochlea. These waves cause the basilar membrane and Organ of Corti to vibrate inside the cochlea and cause the cilia on the hair cells of the Organ of Corti to transduce signals the signals which are sent to the auditory cranial nerve. The cochlea has a tonotopic organization – high frequency sounds stimulate the cells at the basal end of the Organ of Corti and low frequency sounds stimulate the apical end. The wave created from the auditory stimulus moves along the base of the cochlea to its apex; causing high frequency-sounds to be sensed first before low frequency sounds are also detected (Lambell, 2013).

2.4.2 Central Auditory Pathway

The central auditory pathway consists of a web of connections found between parts of the brain. This transmits and analyses information sent to it by the peripheral auditory system. The central auditory pathway begins at the vestibulocochlear or auditory nerve and terminates at the auditory cortex in the brain. Structurally, the central auditory system comprises of the auditory nerve, cochlear nucleus, superior olivary nucleus, inferior colliculus, lateral lemniscus medial geniculate body of the thalamus, and auditory cortex. The peripheral and central auditory pathways are connected by the spiral ganglion. The auditory nerve travels through the internal auditory canal to the cochlear nucleus in the brainstem. The cochlear nucleus is found on the dorsolateral side of the brainstem and is connected to the superior olivary complex by nerve fibers. The superior olivary complex is consists of three nuclei. These are, the lateral superior olive, medial superior olive, and medial nucleus of the trapezoid body which is surrounded by the periolivary nuclei.

The superior olivary complex projects bilaterally to the nucleus of the lateral lemniscus and contralaterally to the inferior colliculus. The medial geniculate body transmits its ascending output to the ipsilateral auditory cortex where the signal undergoes sensory processing. These major ascending pathways are coupled with modulatory descending pathways including one from the cortex to the cochlear hair cells. Overall, the central auditory pathway is extremely complex and interconnected with excitatory and inhibitory projections to shape the auditory input (Lambell, 2013).

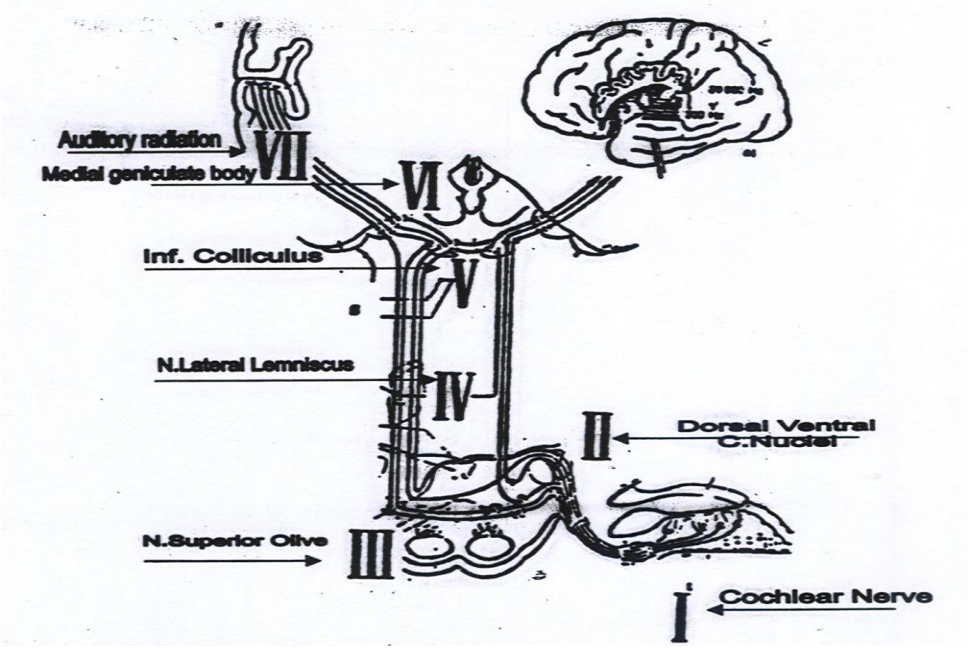

Figure 2.1 Anatomical locations of Auditory Brainstem Generators (AlRouq, 2012)

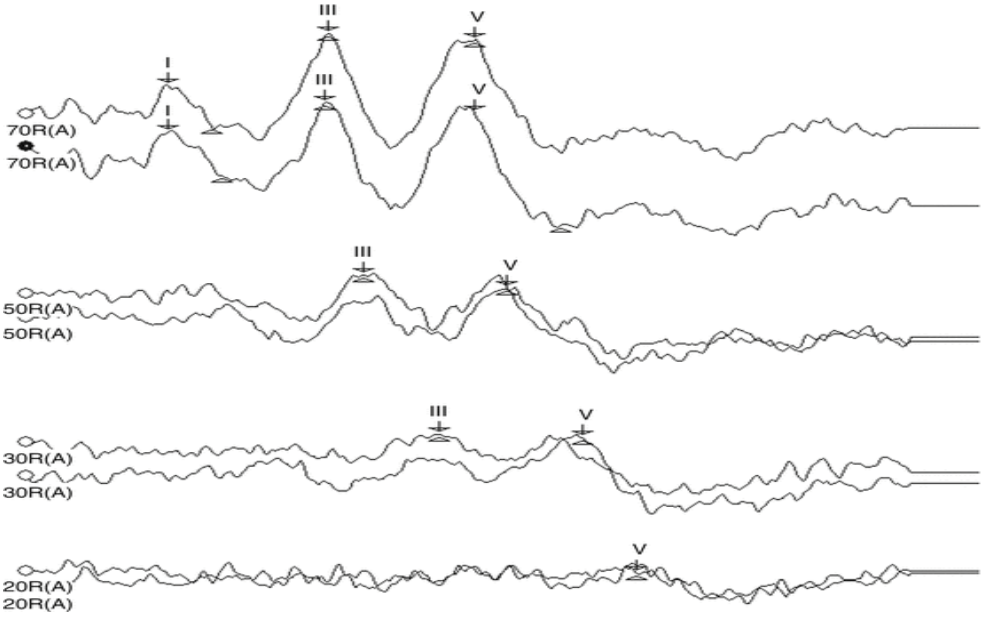

Figure 2.2 Typical ABR waveform of a neonate with normal hearing (Jacobson & Hall, 1994)

2.5 AUDITORY BRAINSTEM RESPONSE MEASUREMENT PARAMETERS

2.5.1 Latency

Jacobson and Hall (1994) reported that, the latency of ABR which is the time taken for each waveform to occur after a stimulus presentation is affected by variables such as development of the auditory system and stimulus intensity. According to Ness (2009) latencies of waves are determined by how the stimulus travels through the structures of the ear and the brainstem. Ness (2009) noted that, latency values will occur within a designated period if there is no obstruction in the auditory pathway from the outer ear through to the brainstem. However, any lesion along of these structures would cause a prolongation of the latency and waveforms can disappear altogether. The absolute latencies of all waves increase with decreasing stimulus intensity. Shivaji, et al. (2013) attributed increase in wave I latency in newborns to factors such as immaturity of basal part of basilar membrane due to low stiffness, immaturity of the hair cell auditory synaptic function and mechanical attenuation of sound in the middle ear.

2.5.2 Intensity

Jacobson and Hall (1994) reported that, changes in stimulus intensity directly affect response latency. Increase in intensity corresponds to decrease in wave component latency. The ABR exhibits all the waveform components at high intensity (70dB to 90 dBnHL) to produce the largest amplitude and shortest latency waves (Atcherson, 2012). These high intensities help in stimulating numerous auditory nerve fibers. With decreasing intensity levels, waves I and III drop out first except wave V which often remains and exhibit delayed latencies (Atcherson, 2012).

2.5.3 Amplitude

Jiang, Wu and Zhang (1991) examined the effect of click on ABR wave amplitude. The amplitude change was examined in 80 neonates with normal hearing. Results from the study indicated a decrease in amplitude values with increasing repetition rate for wave I and V. The study concluded that, the amplitude of wave I is affected by the repetition rate slightly more than wave V. A typical amplitude recording from a newborn using a 70dB normal hearing level click stimulus at a rate of 10/sec is approximately 0.35 and 0.40μV for waves I and V respectively (Jacobson and Hall, 1994). The amplitude is the magnitude or power of the response and is a vertical measure of difference between the peak of a wave and its following trough. Less emphasis is placed on the amplitude values of the waveforms compared to the latency values due to variability among subjects (Ness, 2009). The amplitude ratio is affected by stimulus intensity, presentation rate, electrode type, scalp location and age (Weber and Jacobson, 1994).

2.6 FACTORS AFFECTING AUDITORY BRAINSTEM RESPONSE RESULTS

2.6.1 Age and Gender

Angrisani et al., (2012) observed that there are few studies that seek to determine the influence of gender on the results of the ABR in newborns. They further noted that the results are conflicting, because while some conclude that there are important differences between the sexes, others suggest that such differences though small, have no relevant clinical expression.

Li et al., (2013) and Angrisani et al., (2012) compared ABR in healthy term neonates and found that males had delayed latencies for waves latencies III, V and inter-peak latencies I-III, III-V, and I-V intervals and smaller amplitudes for wave III and V than females. This implies that

gender exerts significant influence on ABR with shorter responses in females. In general ABR in neonates is different from adults because maturation of their auditory system is not complete at birth (Atcherson, 2012). As a result, ABR changes significantly early in life and achieves maturity (adult stage) by 18 months of age (Gelfand, 2009). Whereas ABR waves I, III, and V are visible in newborns, absolute latencies of waves III and V as well as the inter-wave latencies are however delayed compared to adult values (Jacobson and Hall, 1994). Additionally, as noted by Sininger (1992), waves I and III achieve adult latency at about 3 months and 16 months respectively while wave V latency achieves adult characteristic between 18 to 36 months.

2.6.2 Body Temperature

Bridger and Graham (1985) recorded a significant latency difference as a result of raised body temperature on ABRs in nine neonates with normal hearing. The results from the study showed the mean latency for wave V decreased from 5.84 ms (s.d. 0.193) to a mean of 5.62 ms (s.d. 0.185) for males and from 5.87 ms (s.d. 0.105) to 5.68 ms (s.d. 0.105) for females. The study concluded that nerve conduction rates in the auditory pathway are influenced by body temperature and that this may have to be taken into account when interpreting ABR recordings. In a similar study, Rodriguez et al., (1999) examined the effects of temperature on ABR in neonates and recorded significant increases and decreases with cooling in ABR latencies and amplitudes respectively. Additionally, Arnold (2007) reported that decrease in body temperature below 36°C causes an increase in ABR inter-peak latency. This effect results in slowed neural conduction velocity and synaptic transmission. Arnold (2007) subsequently suggested temperature measurements prior to ABR evaluation in newborns with low birth weight since they are prone to hypothermia. According to Jacobson and Hall (1992), effects of decreasing

body temperature (below 36°C) will prolong absolute and relative latency and decrease response amplitude.

2.6.3 Hearing status

Jiung-Chih, Hsu-Chueh and Juen-Haur (2008) evaluated the auditory brainstem responses in patients with asymmetric hearing loss. In the study, hearing level on ipsilateral ABR was carried out by multivariate linear regression for 245 patients comprising 106 males and 139 females with asymmetric hearing loss. Results from the study indicated that, Waves III and V latencies of patients with asymmetric hearing loss were significantly affected. The study concluded that, effect of clinical factors on ABR were different between patients with ASHL and normal-hearing subjects.

Hearing loss could attenuate the perceived intensity level of the stimuli (Atcherson, 2012). This could result in prolongation of latencies of the ABR waves. Conductive and sensorineural losses attenuate the strength of the intensity reaching the cochlea resulting in delay latency-intensity functions (Gelfand, 2009). Similarly, Sininger (1992) reported that peripheral hearing loss can distort waveform morphology, especially for earlier peaks and can decrease peak amplitudes and increase expected latencies.

2.7 STIMULUS PARAMETERS

2.7.1 Stimulus type

According to Hall (2007), early latency auditory evoked responses (AERs) are recorded with very brief (transient) stimuli with an abrupt onset. Hall (2007) noted that the brief duration of

click, which has an abrupt onset, is the most commonly used stimulus for ABR measurement. The rapid onset of the transient stimulus helps in producing the synchronous firing of numerous auditory neurons. The rise of a click is sufficiently rapid to synchronize the discharges of a large number of neurons (Fowler and Durrant, 1994). A click stimulus is an electrical broadband signal containing a wide range of frequencies in its spectral presentation with typically 0.1ms in duration (Petrak, 2000).

This range of frequencies activates the cochlea specifically, the hair cells, over an extensive region of the basilar membrane (Petrak, 2000). Jacobson and Hall (1994) noted that, clicks have their energy concentrated in the high frequencies and therefore provide information about peripheral hearing in the 2000Hz to 4000Hz range. Hall (2007) observed that, higher frequencies in the click acoustic spectrum are responsible for generating the ABR in the normal ear.

2.7.2 Stimulus Rate

Hall (1992) noted that in the selection of stimulus rate for any AEP measurement, rates such as 21.1/sec or 37.7/sec. should be selected in order to minimize the possibility of power line interference. Repetition rate can be manipulated to permit fast data collection in a short amount of time.

Lasky (1997) showed that, auditory evoked brainstem response latencies increased and amplitudes decreased with increasing stimulus repetition rate for neonates. The study recorded delayed wave V latency in newborns. The study attributed these findings to human developmental differences in adaptation to repetitive auditory stimulation at the level of the brainstem. Additionally, Parthasarathy, Borgsmiller and Cohlan (1998), evaluated the effects of

stimulus repetition rate on ABR in normal hearing neonates. Results from the study showed delayed ABR wave V latency in neonates. The study concluded that, increasing stimulus repetition rate produced greater wave V latency shift in neonates.

2.7.3 Stimulus Polarity

Lima et al., (2008) investigated the influence of the click stimulus polarity in the study of ABR audiometry at different intensities, using insertion-canal earphones on a population of 33 neonates without any history of hearing related pathology. Findings from the study showed that, absolute latencies of wave V were lower in the rarefaction polarity phase of the signal compared to condensation and alternate polarities.

Condensation, rarefaction and alternating polarity signals are used in ABR assessment (Hall, 2007). According to Petrak (2000), rarefaction is produced by pulling the earphone diaphragm away from the tympanic membrane and condensation is formed by pushing diaphragm toward the tympanic membrane. Alternating polarity is a switching between condensation and rarefaction polarities at subsequent stimulus presentations (Petrak, 2000). Silman and Silverman (1991) indicated that rarefaction clicks tend to be associated with shorter absolute peak latencies than condensation while Atcherson (2012) observed that the latencies do not change much with the different phases.

2.7.4 Transducer type

Van, Sammeth, Hall and Peek (1992) compared ER-3A insert earphones and supra-aural earphones (TDH-39P and TDH-49P) in normal hearing neonates. Results from the study revealed significant differences among the earphones. The ER-3A earphones produced a latency

delay, relative to the TDH earphones, that varied from about 0.8 to 1.0 millisecond. The study recommended collection of normative data with the ER-3A earphones. According to Hall (2007), the purpose of this acoustic delay is to separate in time the stimulus-related artifact produced by the transducer and the desired ABR. In a similar study, Beauchaine, Kaminski and Gorga (1987) measured click-evoked ABR in a group of normal-hearing neonates using a Beyer DT48 circumaural earphone and an Etymotic ER-3A insert earphone. Results from the study showed absolute response-component latencies differed significantly by an amount equivalent to the travel time introduced by the insert earphone's sound-delivery tube. The study concluded that the insert earphone is a viable transducer for clinical ABR evaluations. However, a temporal correction may be necessary to account for the difference between the insert earphone and the circumaural earphone. Petrak (2000) further noted that, insert earphones have several advantages including disposable neonatal eartips, reduced stimulus artifact, decreased background noise, increased interaural attenuation and decreased likelihood of collapsed canals.

2.7.5 Noise

Sanchez and Gans (2006) evaluated the effects of noise on the ABR. In the study, auditory brainstem responses from 20 neonates were recorded during quiet and active behavioral conditions. Findings from the study indicated that, ABR recorded during the quiet condition resulted in minimal differences in wave latencies. However, during the active behavioral condition, there were significant differences in the recorded wave latencies and difficulty in preserving the evoked potential. The study concluded that noise had a detrimental effect on waveform morphology of the ABR which could lead to difficulty in ABR interpretation. According to Marcoux and Kurtz (2012), noise refers to interference from electro-magnetic and

myogenic sources, which make it difficult to recognize and detect the true response in ABR waveforms. Marcoux and Kurtz (2012) further asserted that, there is a significant effect of noise on ABR measurement when the amplitude of the recorded response exceeds 20uv. Muscular activity from newborns produce significant artifact that may interfere with the ABR. This is always present in non-relaxed neonates and normally disappears as the subject sleeps particularly under sedation (Sokolov et al., 2005).

2.7.6 Recording Factors

2.7.6.1 Filter

Sininger (1995) examined the effects of filtering on ABR and background noise in neonates. The study compared the effects of 30 and 100Hz high-pass filters on ABR amplitude and response in full-term neonates using clicks. Results from the study indicated that, energy in the infant ABR is concentrated below 100 Hz. Additionally, the high-pass filter of 30 Hz used produced delayed ABR amplitude and this enhanced the overall signal-to-noise ratio measured as compared to the 100Hz high pass. The study concluded that filter choice can affect the validity and efficiency of ABR measurement. In a similar study, Diao et al., (2011) compared the thresholds of click and tone burst ABR with two different filter settings evaluated its effect on waveforms and recorded thresholds with filter settings of 30 - 1500 Hz and 30 - 3000 Hz. Results from the study indicated that thresholds of tone burst ABR with filter settings of 30 - 3000 Hz were higher than that with filter settings of 30 - 1500 Hz. Additionally, the waveform of ABR with filter settings of 30 - 1500 Hz was smoother than that with filter settings of 30 - 3000 Hz at the same stimulus intensity. The study concluded that, filter setting of 30 - 1500 Hz helped in improving the accuracy of frequency specificity auditory brainstem response for neonates hearing assessment.

According to Sininger (1995), filtering is used in evoked-potential measurements to reduce background noise to suppressed unwanted spectral components without altering neural activity. In ABR measurement, high and low-pass filters pass bands of frequencies by rejecting electrical energy at certain frequencies and passing energy at other frequencies. As explained by Hall (2007), high-pass filters reject lower frequency energy and pass higher frequency energies, while while the opposite is true for low-pass filter. A band-pass filter rejects energy below and above a certain cut off. According to Hall (2007), filter settings of 30Hz to1500 Hz or 3000 Hz will minimize significantly the background noise.

2.7.6.2. Signal Averaging

Signal averaging is a method used to extract the ABR signal from the background noise. ABR signal is time–locked to stimulus on set, while the noise interference occurs randomly (Gelfand, 2009). This implies that ABR signals occur at the same time following the stimulus onset regardless of the noise pattern. Alwan (2012) observed that, signal averaging is done by introducing a large number of stimuli in repetitive manner, termed as “sweeps”. Responses are then averaged together to obtain a final ABR waveform. The random noise cancels out while the evoked response is maintained because it is the same in every sweep. The higher the number of sweeps, the better signal-to-noise ratio (SNR) is achieved and a clearer ABR waveform is obtained (Alwan, 2012). Similarly, Marcoux and Kurtz (2012) reported that, increasing the number of stimulus presentations or sweeps improves waveform morphology and averaging can be terminated as soon as a clear auditory brainstem response waveform is visualized.

2.7.6.3 Analysis Time (Epoch)

The analysis time or epoch is the period of time after the stimulus is presented in which data are collected and appear in the analysis window. Petrak (2000) noted that the analysis window should be long enough to display the entire response since neonates have longer latencies for wave V than adults. Therefore, analysis window should be least 20-22 msec. Similarly, Hall (2007) observed that, in auditory evoked measurement, the analysis time should be long enough to encompass the response of interest under all test conditions. According to Hall (2007), for ABR evoked by click, 15-20 milliseconds analysis time is recommended since there are many circumstances that will delay wave V. Factors contributing to such a delay include immature central nervous system (CNS) function in children, neuropathology, low stimulus intensity and peripheral hearing impairment.

2.7.6.4 Sweeps

The term sweep refers to each time a stimulus is presented. Hall (2007) reported that, with each presentation, the system sweeps through the analysis time looking for a response. The number of sweeps equals the number of stimuli. According to Hall (2007), in a quiet environment, it is possible to generate ABR from neonates with normal hearing sensitivity after 500 sweeps using a click stimulus when the SNR is adequate. However, neonates with hearing loss may need an average of 3000 or more sweeps to enhance the response (Hall, 2007). Similarly, Petrak (2002) noted that more sweeps (between 1500-2000) are required in noisier backgrounds and it is permissible to halt data collection after 1000 sweeps if a well defined ABR waveforms and peaks emerges.

2.7.6.5 Electrode Types and Application

Hall (2007) recommended the following guidelines to ensure a successful ABR measurement

- Consistent placement of electrodes among neonates
- Anatomically accurate placement of electrodes
- Low inter-electrode impedance (less than 5000ohms)
- Secure and consistent attachment of electrodes throughout the test session
- Minimal discomfort to the subject

Similarly, Sininger (1992) observed that changing electrode placement affects response amplitude and latency. Electrode impedance can affect peak amplitude and distort waveform morphology. Sininger (1992) recommends that, electrodes are placed either at the ear lobe or mastoid. In ABR measurement it is important to select electrodes designed specifically for neonates. The neonate's skin should be carefully and gently apply with gel before the electrodes are applied. Inter-electrode impedance should be less than 5000ohms to prevent distortion of waveform morphology (Petrak, 2000).

2.7.7 Studies on Normative Data

Various studies have been done on developing reference values for ABR testing. Laura, Guilhoto, Quintal and Da Costa (2013), researched into ABR latencies on 47 neonates using 80 dBHL clicks of alternating polarity at a rate of 10/sec. The study recorded an increase in latency values for neonates. Table 2.2 shows the mean of the latencies in milliseconds recorded from the study (Laura, Guilhoto, Quintal and Da Costa (2013).

Table 2.2: Mean of the latencies of neonates recorded

Intensity (dBHL)	Wave I(ms)	Wave III(ms)	Wave V(ms)	I-III(ms)	III-V(ms)	I-V (ms)
	Mean ± s.d	Mean ± s.d	Mean ±s.d	Mean ± s.d	mean ± s.d	Mean ± s.d
80	1.79 ± 0.20	4.54 ± 0.31	6.75 ± 0.38	2.75 ± 0.36	2.22 ± 0.22	4.97 ± 0.43

A similar study was conducted by Shivaji et al., (2013) to develop normative data for monaural recordings of auditory brainstem in neonates with normal hearing. ABR was performed on 40 neonates using 70 dBHL clicks of alternating polarity at a rate of 11.1/sec and parameters required to establish a baseline data such as absolute latencies, amplitudes, amplitude ratios and Inter- peak latencies were assessed for their normative values. Table 2.3 shows the mean of the latencies in milliseconds recorded from the study (Shivaji et al., 2013).

Table 2.3: Mean of the latencies and standard deviations of neonates recorded

Intensity (dBHL)	Wave I(ms)	Wave III(ms)	Wave V(ms)	I-III(ms)	III-V(ms)	I-V (ms)
	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d
70	1.66 ± 0.23	3.65 ± 0.39	5.59 ± 0.71	2.04 ± 0.26	1.98 ±0.36	4.03 ± 0.35

ABR parameters show variation in values depending on age, myelination process, maturation of auditory pathway, environmental factors and laboratory setup. The study concluded that each laboratory should have its own normative data, which can be used as a baseline data for screening of patients with hearing loss.

Costa, Aurelio, Braz and Rodrigues (2012) researched into standardization of auditory brainstem response in newborns. ABR was performed on 40 neonates with different age groups using

80dBHL clicks of rarefaction polarity at a rate of 27.7. The study recorded an increase in absolute and inter-peak latency values for neonates. Table 2.4 shows the mean of the latencies in milliseconds recorded from the study (Costa et al., 2012).

Table 2.4: Mean of the latencies and standard deviations of neonates

Intensity (dBHL)	Wave I(ms)	Wave III(ms)	Wave(ms)	I-III(ms)	III-V(ms)	I-V (ms)
	Mean ± s.d	Mean ± s.d	mean ± s.d	Mean± s.d	Mean± s.d	Mean ± s.d
80	1.65 ± 0.05	4.54 ± 0.18	6.88 ± 0.20	2.90 ± 0.20	2.33 ± 0.14	5.23 ± 0.23

Rosa, Suzuki, Angrisani and Azevedo (2014) studied absolute latencies and inter-peak latencies of ABR in neonates. ABR was performed in different age groups of neonates using 80dBHL clicks of rarefaction polarity at a rate of 27.7 per second. The study recoded a decrease in the absolute latencies of the waves I, III and V, as wells as in inter -peak I-III, III-V and IV. The study concluded that, the higher the age at which neonates were being evaluated, the shorter their absolute and inter-peak latencies become as shown in Table 2.5 (Rosa et al., 2014).

Table 2.5: Mean of the latencies and standard deviations of neonates

Intensity (dBHL)	Wave I(ms)	Wave III(ms)	Wave V(ms)	I-III(ms)	III-V(ms)	I-V (ms)
	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d	Mean ± s.d
80	1.79 ± 0.09	4.62 ± 0.20	7.05 ± 0.28	2.83 ± 0.20	2.42 ± 0.22	5.23 ± 0.24

Issa and Ross (1995) researched into the procedure for assessing ABR latency in neonates. In the study a new normative data set was established by measuring ABR absolute and interpeak

latencies in 374 neonates in different age groups with normal hearing thresholds ABR and no risk factor for hearing impairment or neurological abnormality. The study concluded that latency values of neonates decreases with increasing age and stimulus intensity. Ness (2009) noted that, absolute latencies which exceed 2 standard deviations are audiologically significant. The inter-peak latency (IPL) is the time difference in absolute latency between waveforms. The waves I – III, III – V, and I – V inter-peak latencies are computed when all waveforms are labeled in terms of absolute latency. These values are then compared to normative values to determine if they occur within normal duration. Ness (2009) showed, IPL for waveforms I – III and III – V as 2.0 ms and 2.0 ms respectively. The IPL latency for waveform I – V is approximately 4.0 ms. The wave I-V IPL latency is prolonged in newborns due to delayed myelination of auditory pathway and improper efficacy of higher neurons (Shivaj et al., 2013). According to Atcherson (2012), inter-peak latencies which exceed 2 standard deviations are diagnostically significant. The waves I – III exhibits neural activity in the cochlear nerve and lower brainstem. The waves III – V interval represents activity within the brainstem. The waves I – V interval shows the overall activity from the cochlear nerve and structures of the lower brainstem response to auditory stimuli (Hood, 1998).

2.7.8 Guidelines for Developing Normative Data

There is no fixed guideline for developing normative data for clinical ABR applications (Sininger, 1992). The American Electroencephalographic (EEG) Society advocates that published data could be utilized with precaution, however, the type of hardware and clinical needs require each laboratory to develop its own clinical norms for ABR.

According to Sininger (1992), the following guidelines could be employed in developing clinical norms for ABR:

- Select a set of recording and stimulus parameters according to the type of client or patient to be evaluated and the information required.
- Review literature for published databases that utilize similar recording and stimulus parameters.
- Establish normalized hearing levels using the stimulus parameters and behavioural hearing thresholds for each stimulus, and conduct threshold determination procedure in a quiet environment such as a hearing test booth
- Run ABR tests on a group of young subjects (a minimum of 10 females and 10 males) who have normal hearing and no history of ear or hearing related disorders to validate the recording procedure.
- Compare the measured response parameters to the published data. Data for most "normal" subjects should fall within 2 standard deviations of the published data. Differences of more than 5% outside of this range should be investigated.

According to Hall (2007), due to factors such as time and subject availability, normative data are generated from a small group of subjects with normal hearing, using the same protocol. Additionally, the sample size of subjects used in developing clinical norms for ABR is selected on the basis of convenience rather than the use of statistics (Hall, 2007). Silman and Silverman (1991) reported that a small sample size of 10-30 subjects with normal hearing thresholds are used in most clinical laboratories in developing clinical norms for ABR.

2.7.9 Parameters for Developing Normative Data

The following parameters in developing the ABR norms conducted by Shivaji et al., (2013), in establishing normative data for infants were used in the study.

- Most prominent latency of waves I, wave III and wave V in milliseconds (ms) of each ear separately.
- Amplitudes in microvolt of wave I and wave V.
- Amplitude ratio.
- Inter-peak latencies of wave I, III and V in sm.

The response from the above parameters were analyzed and compared at 70dBnHL stimulus intensity level. Similarly, Sininger (1992) reported that, in establishing clinical norms for ABR, response parameters such as general waveform morphology, wave latencies, inter-peak latencies, amplitude and relative amplitudes could be evaluated. According to Sininger (1992), these response parameters can be influenced differently by factors such as age, gender, hearing status of subject, stimulus factors and recording factors.

2.8 CLINICAL APPLICATION OF AUDITORY BRAINSTEM RESPONSE

Shivaji, et al., (2013) reported that clinically ABR is used for estimating hearing loss, especially in difficult-to-test populations such as premature newborns and children with delayed milestones, attention deficit and other sensory or motor impairment who cannot complete a traditional behavioural audiological evaluation. Additionally, ABR can be used as a clinical measure to assess or determine the integrity of the auditory function from the peripheral auditory system to the level of the lower brainstem.

According to Alwan (2012), ABR is a very valuable clinical tool for otoneaurological assessment or in the identification of retrocochlear pathologies of the auditory system, such as brain tumors, auditory neuropathy and multiple sclerosis that affect the anatomical structures located above the level of the cochlear. Gelfand (2009) noted that ABR is employed in intraoperative monitoring during surgical procedures that may damage the eighth nerve. Martin and Shi (2009) further explained that, intraoperative monitoring of auditory evoked potentials provides the surgical team with early warning signals that will enabled them avoid damage to the auditory pathway and reducing the likelihood of causing hearing loss. Procedures that place the auditory nerve at risk include resection of vestibular schwannomas, vestibular nerve section and microvascular decompression of cranial nerves V, VII, VIII and IX (Martin and Shi, 2009). Although ABR provides information regarding auditory function and hearing sensitivity, it is not a replacement for a hearing test. ABR waveform results should therefore be used in addition to other test batteries.

2.9 RESEARCH GAP

Clinical normative data on neonates have been established in many developed countries (Laura, Guilhoto, Quintal and Da Costa, 2013; Shivaji et al., 2013; Costa et al., (2012), Aurelio et al., 2012; Rosa et al., 2014; Issa and Ross, 1995). ABR normative data for neonates is currently unavailable at the Hearing Assessment Centre-KBTH, Ghana.

There is the likelihood that inter-laboratory differences such as testing environment, tester and protocol setting may result in differences between the clinically developed normative data and the published data. This could lead to discrepancies in interpretation of waveforms that may

result in wrongful identification and reporting of neonatal hearing loss. Therefore, to ensure objective and valid interpretation of auditory sensitivity of neonates in KBTH, it is important to establish a clinical normative data for neonate ABR testing. It is based on this necessity that the current study aimed to develop clinical normative data for neonates.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This Chapter presents the methods and techniques for the conduction of the study including research design, population, sample and sampling technique, instrumentation, data collection procedures and data analysis.

3.2 RESEARCH METHOD

The study adopted a quantitative approach emphasizing objectivity and quantification of a phenomenon. According to Creswell (2005), the quantitative approach to studies is a method which provides for decisions on what to study, asking of specific narrow questions, collection of numeric (numbered) data, statistical analysis of numbers and conducting inquiries in an unbiased, objective manner. This approach was therefore adopted in this study as it facilitated a comprehensive presentation and analysis of the data collected.

3.3 STUDY DESIGN

A prospective study design was adopted for the study. It is an analytical study designed to determine the relationship between a condition and a characteristic shared by some members of a group. The design facilitated the comprehensive relation of the clinically established norms to the published data and the effect of gender on latencies of neonates.

3.4 POPULATION

The population for the study constituted of neonates aged between 2-8 weeks reporting to the Hearing Assessment Centre (HAC) of KBTH for newborn hearing screening (NHS).

3.5 SAMPLE SIZE AND SAMPLING TECHNIQUES

The sample size for the study constituted 30 infants (15 males and 15 females) who were selected purposively. Purposive sampling allows handpicking of cases for inclusion in the sample on the basis of possession of required particular characteristic(s) (Cohen, Manion & Morrison, 2007). The subjects were handpicked from the population based on the inclusion criteria requirements.

3.6 STUDY SITE

The study was conducted at the Hearing Assessment Centre (HAC) of the KBTH that serves as the main referral centre for the regional and district hospitals. The hospital is also the teaching center for the various Schools of the College of Health Sciences, which includes the School of Biomedical and Allied Health Sciences. Currently, the HAC of KBTH is the only health facility with ABR test facility.

3.7 INCLUSION AND EXCLUSION CRITERIA

3.7.1 Inclusion Criteria

A pass in transient evoked otoacoustic emissions (TOAE) test and a normal tympanogram measured with 1000Hz probe tone. The inclusion criterion was applied to ensure normal hearing participants were recruited for the study.

3.7.2 Exclusion criteria

The following criteria were used to exclude non-participants:

- Participants with histories of any ear or hearing related disorders
- Participants aged outside the age bracket of 2 to 8 weeks.
- Participants with abnormal tympanograms

3.8 INSTRUMENTATION

All instruments used in this study were within calibration. The following instruments were utilized in the process of conducting this study:

3.8.1 Welch Allyn Otoscope

This was used to visually examine the external auditory canal of participants for any occlusion and or otitis externa.

3.8.2 GSI Tympstar Version 2 Middle-Ear Analyzer

This equipment is a computer-based admittance instrument designed for use in clinical and/or research setting. Admittance (Y) and its components susceptance (B) and conductance (G) may be measured with probe tone frequencies of 226Hz, 678Hz and 1000 Hz. The battery of tests include: diagnostic tympanometry, aural/acoustic reflex threshold and decay measurements, Eustachian-tube function testing, acoustic reflex latency testing, acoustic reflex sensitization and multiple frequency tympanometry (250 Hz to 2000 Hz). The tympanometric measurement results are automatically scaled and presented in equivalent ml of compliance at “Y”, 226 Hz. All “B and G” measurements and measurements performed at probe tone frequencies of 678 Hz and 1000 Hz are expressed in mmhos and test results are displayed in real time.

3.8.3 AuDX Otoacoustic Emissions Test Device

The AuDX otoacoustic emissions test device system utilizes a combination of hardware and software to produce a controlled acoustic signal in the ear canal. The resulting evoked emission generated by cochlea outer hair cells is measured by the device which collects and averages sampled data until specified measurement parameters are achieved. For transient otoacoustic emissions (TEOAEs/TE), these measurement parameters include:

- acoustic energy generated by the cochlear outer hair cells in response to stimulation (TE),
- the average amplitude of the background noise measured during the TEOAE test (NF)
- the dB difference between the transient evoked otoacoustic emission and the noise floor amplitudes (TE-NF)

3.8.3.1 TEOAE Pass/Refer Criteria and Test Protocol

The TEOAE pass/refer criteria and test protocols utilized in TEOAE are summarized in Tables 3.1 and 3.2 respectively. The Block diagram of OAE measuring system is shown in Figure 3.1.

Table 3.1: TEOAE Pass/Refer criteria

Parameter	Criterion
Reproducibility	70% or greater
TE amplitude	0 dB SPL or greater
TE-NF	6 dB or greater

Table 3.2: TEOAE test protocol

Parameter	Setting
Frequency Band	1286-3536 Hz
Stimulus Intensity	80 dB SPL
Start time	3.5 ms
End time	12 ms
Ramp	1 ms
Samples	32
Maximum # of samples	512
Stopping rule-reproducibility	70%
Stopping rule-TE amplitude	0 dB SPL or greater
Stopping rule-TE-NF	6 dB or greater
Stopping rule- NF	-10 dB SPL or lower
Artifact rejection threshold	20 mPa

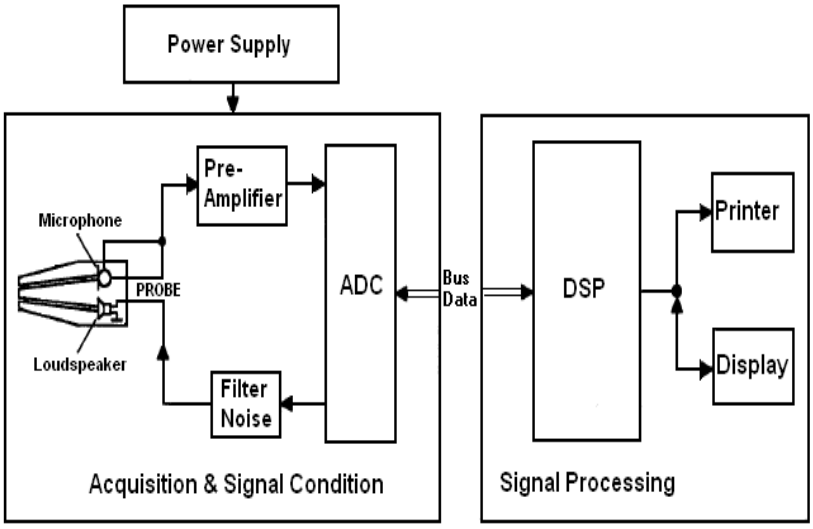

Figure 3.1: Block diagram of OAE measuring system. ADC=Analog-to-digital converter DSP=Digital Signal Processing

3.8.4 Smart EP Auditory Brainstem Response Equipment

The smart Evoke Potential (EP) equipment of Intelligent Hearing Systems (HIS) connected to ER 3A insert earphones with Ambu Neuroline 720 single patient disposable surface disc electrodes was used on standard scalp locations in an acoustically treated room. Block diagram for the ABR equipment used for the study is shown in Figure 3.1.

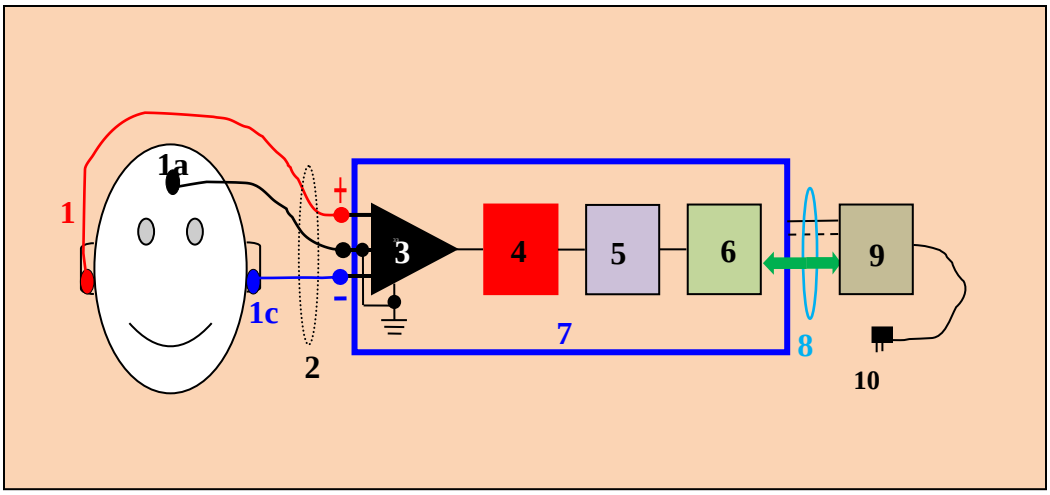

Figure 3.2: Block diagram of ABR

1a – non-inverting (+) electrode (shown placed on higher forehead), 1b – ground electrode (shown placed on the right ear lobe), 1c – inverting electrode (shown paced on the left ear lobe), 2– electrode lead wires (leads), 3 – differential preamplifier, 4 – band-pass filter (30-1500 Hz), 5 – power amplifier, 6 – analog-to-digital (A/D) converter, 7 – interface module, 8 – Interface cable, 9 – personal computer, 10 – power cord.

3.9 DATA COLLECTION PROCEDURE

3.9.1 Procedure

The parents of sampled babies were educated on the study and guided to complete consent forms. Only babies with passes in otoscopic examination, TEOAE test and normal tympanograms were recruited for the study. Data on demographic characteristics of participants were also recorded.

The ABR tests were performed using the smart EP equipment in an acoustically treated room (ambient noise=31 dB). The alternating polarity click stimulus was introduced and presentation rate of 21.1 clicks per second with a recording window of 12ms. For the analysis of the tracing generated, a total of 2,048 clicks were presented twice so that reproducibility between tracings could be observed. The ER 3A insert earphones were used, and recordings of responses were made using surface electrodes (disposable), positioned according to the international 10-20 system (Cz: front; A1: right lobe, and A2: left lobes), adapting the impedance below 3 kΩ. The skins of the neonates were cleaned with a gel for better conduction. All examinations were performed with the babies in natural sleep. A presentation level of 80 to 30 dBHL in 10 dB decrements was utilized.

Table 3.3: ABR Test Protocol

Table 3.3 presents testing protocol utilized in data collection

Parameter	Setting
Stimulus	0.1 milliseconds Click
Rate	21.1/sec
Polarity	Alternating
Transducer	Insert Earphones
Filters	30-1500 Hz
Intensity	80 dB HL down to 30 dB HL
Runs	2
Analysis time window	12 milliseconds
Sweeps	2048
Electrode montage	Ipsilateral

3.10 DATA ANALYSIS

ABR with alterations as a result of conductive hearing loss, sensory hearing loss or neural dysfunctions were not included in data analysis:

- Conductive alterations were identified by an increment in the absolute latencies of waves I, III and V with normal inter-peak latencies.
- Sensory loss was considered when ABR thresholds were above 30 dBnHL with absolute latencies and inter-peaks of the waves I, III and V within the normal range.
- Neural dysfunctions were considered upon a presentation with alteration of the absolute latencies of waves I, III and/or V as well as the inter-peaks.

The upper latency limits for categorizing “normal” and “abnormal” ABR waveforms were set on the basis that “normal” waveforms (absolute and inter-peak latencies) should fall within 2 standard deviations of published data.

Data was summarized and analyzed using descriptive and inferential statistics (independent t-test, mean, and standard deviation). This allowed an in-depth understanding of the patterns of the waveform distribution and their relations.

3.11 DATA MANAGEMENT PLAN

Data on the auditory status of participants was kept confidential by identifying babies with reference codes. The data will be managed by the Department of Audiology, speech and language therapy and utilized for research and development purposes.

3.12 INFECTION CONTROL

To curb cross infection, disposable (ER 3A) insert earphones and surface electrodes were utilized in data collection. Furthermore, the germ-X Hand Sanitizing Wipes were used before and after testing a participant.

3.13 ETHICAL CONSIDERATION

Ethical clearance approval for the study was obtained from the Ethics and Protocol Review Committee of the School of Biomedical and Allied Health Sciences and management of the Hearing Assessment Centre (HAC) of KBTH prior to the commencement of data collection. Written informed consent was sought from the guardians of participants before the collection of data.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

The results of the study to develop normative data for objective and valid interpretation of ABR test of neonates for the KBTH HAC are presented in this Chapter. In accordance with literature, the upper latency limits for categorizing "normal" and "abnormal" ABR waveforms were set on the basis that "normal" waveforms (absolute and inter-peak latencies) should fall within 2 standard deviations of published data.

4.2 DEMOGRAPHICS

The age and gender demographics are presented in Table 4.1. A total of 50 subjects (25 males, 25 females) participated in the study. Out of these, only 30 (15 males, 15 females) subjects provided "normal" ABR waveforms for computing the normative data. The ages of participants ranged from 2 to 8 weeks with a mean age of 3.64 ± 1.54 as indicated in Table 4.1.

Table 4.1: The ages of participants

Variable		Frequency	Mean ± s.d
Gender	Male	15	-
	Female	15	-
Age (weeks)	2.0-8.0	30	3.64 ± 1.54

4.3 ABSOLUTE AND INTER-PEAK LATENCIES

The absolute (I, III, & V) and inter-peak latencies (I-III, III-V & I-V) were collected at intensities of 80 dB to 30 dB with a 10 dB decrement for all participants. The results shown in Tables 4.2- 4.3 establish an inverse relationship between wave latencies and intensities.

Table 4.2: Mean values of absolute latencies (Wave I, III & V)

Intensity	Peak I (ms)		Peak III (ms)		Peak V (ms)	
(dBnHL)	Mean	б	Mean	б	Mean	б
30	3.47	0.23	6.05	0.33	8.15	0.28
40	3.05	0.20	5.61	0.31	7.76	0.30
50	2.68	0.21	5.26	0.30	7.40	0.27
60	2.34	0.17	4.93	0.28	7.09	0.22
70	1.99	0.12	4.65	0.27	6.91	0.18
80	1.74	0.10	4.48	0.27	6.74	0.14

Table 4.3: Mean values of inter-peak latencies (Inter-peak I-V, I-III & III-V)

Intensity	Inter-peak I-III (ms)		Inter-peak III-V (ms)		Inter-peak I-V (ms)	
(dBnHL)	Mean	б	Mean	б	Mean	б
30	2.58	0.29	2.10	0.30	4.68	0.32
40	2.56	0.25	2.15	0.32	4.71	0.33
50	2.58	0.26	2.13	0.29	4.71	0.30
60	2.59	0.21	2.16	0.24	4.74	0.20
70	2.66	0.28	2.26	0.24	4.92	0.18
80	2.74	0.29	2.26	0.14	4.99	0.13

4.4 ABSOLUTE, INTER-PEAK MEAN LATENCIES WITH AND IHS DATA

The mean latencies (absolute and inter peak) from the current study compares favorably to the Intelligent Hearing System (IHS) published data. Tables 4.4-4.9 indicates the respective ranges (upper and lower boundaries) defined by 2 s.d of the published data for absolute and inter-peak latency values at test intensities. The latency/intensity function was typically inverse in relationship.

Table 4.4: Comparison of wave I mean latencies with IHS published data

data	intensity (dBHL)	mean ± s.d	2 s.d of published data	
			Lower boundary	Upper boundary
Present study	30	3.47 ± 0.23		
Published data	30	3.11 ± 0.62	1.87	4.35
Present study	40	3.05 ± 0.20		
Published data	40	2.72 ± 0.41	1.9	3.54
Present study	50	2.68 ± 0.21		
Published data	50	2.35 ± 0.44	1.47	3.23
Present study	60	2.34 ± 0.17		
Published data	60	2.14 ± 0.42	1.3	2.98
Present study	70	1.99 ± 0.12		
Published data	70	1.81 ± 0.30	1.21	2.41
Present study	80	1.74 ± 0.10		
Published data	80	1.64 ± 0.43	0.78	2.5

The results showed that the mean latency values of the present study for wave I was within 2 s.d of the published data (Table 4.4). From Table 4.5, the mean latency values for wave III at the various test intensities were within 2 s.d of the published data. Table 4.6 revealed that the mean latency values at the test intensities for wave V were within 2 s.d of the published data.

Table 4.5: Comparison of wave III mean latencies with IHS published data

Data	Intensity	Mean ± s.d	2 s.d of Published Data	
			Lower boundary	Upper boundary
Present study	30	6.05 ± 0.33		
Published data	30	5.64 ± 0.39	4.86	6.42
Present study	40	5.61 ± 0.31		
Published data	40	5.18 ± 0.45	4.28	6.08
Present study	50	5.26 ± 0.30		
Published data	50	4.85 ± 0.37	4.11	5.75
Present study	60	4.93 ± 0.28		
Published data	60	4.46 ± 0.35	3.76	5.16
Present study	70	4.65 ± 0.27		
Published data	70	4.27 ± 0.41	3.45	5.09
Present study	80	4.48 ± 0.27		
Published data	80	4.18 ± 0.32	3.54	4.82

Table 4.6: Comparison of wave V mean latencies with IHS published data

Data	Intensity	Mean ± s.d	2 s.d of Published Data	
			Lower boundary	Upper boundary
Present study	30	8.15 ± 0.28		
Published data	30	7.58 ± 0.48	6.62	8.54
Present study	40	7.76 ± 0.30		
Published data	40	7.23 ± 0.31	6.61	7.85
Present study	50	7.40 ± 0.27		
Published data	50	6.91 ± 0.34	6.23	7.59
Present study	60	7.09 ± 0.22		
Published data	60	6.69 ± 0.30	6.09	7.29
Present study	70	6.91 ± 0.18		
Published data	70	6.51 ± 0.38	5.75	7.27
Present study	80	6.74 ± 0.14		
Published data	80	6.39 ± 0.29	5.81	6.97

Table 4.7: Comparison of inter-peak I-III mean latencies with IHS published data

Data	Intensity	Mean ± s.d	2 s.d of Published Data	
			Lower boundary	Upper boundary
Present study	30	2.58 ± 0.29		
Published data	30	2.53 ± 0.26	2.01	3.05
Present study	40	2.56 ± 0.25		
Published data	40	2.46 ± 0.22	2.02	2.90
Present study	50	2.58 ± 0.26		
Published data	50	2.50 ± 0.30	1.90	3.10
Present study	60	2.59 ± 0.21		
Published data	60	2.32 ± 0.25	1.82	2.82
Present study	70	2.66 ± 0.28		
Published data	70	2.46 ± 0.26	1.94	2.98
Present study	80	2.74 ± 0.29		
Published data	80	2.54 ± 0.24	2.06	3.02

Table 4.7 depicted that the mean inter-peak I-III latency values at the various test intensities were within 2 s.d of the published data. The mean inter-peak iii-v latency values at the respective test intensities were also within 2 s.d of the published data (Table 4.8).

From Table 4.9, the mean latency values for inter-peak I-V of the present study at the respective intensities were within the upper and lower boundaries (defined by 2 s.d of the published data). The variations of the absolute latencies, and inter-peak latencies of the current study and the HIS published data are shown Figures 4.1 and 4.2 respectively.

Table 4.8: Comparison of wave III mean latencies with IHS published data

Data	Intensity	Mean ± SD	2 s.d of Published Data	
			Lower boundary	Upper boundary
Present study	30	2.10 ± 0.30		
Published data	30	1.94 ± 0.24	1.46	2.42
Present study	40	2.15 ± 0.32		
Published data	40	2.05 ± 0.26	1.53	2.57
Present study	50	2.13 ± 0.29		
Published data	50	2.06 ± 0.22	1.62	2.50
Present study	60	2.16 ± 0.24		
Published data	60	2.23 ± 0.20	1.83	2.63
Present study	70	2.26 ± 0.24		
Published data	70	2.24 ± 0.21	1.82	2.66
Present study	80	2.26 ± 0.14		
Published data	80	2.21 ± 0.22	1.77	2.65

Table 4.9: Comparison of wave V mean latencies with IHS published data

Data	Intensity	Mean ± SD	2 s.d of Published Data	
			Lower boundary	Upper boundary
Present study	30	4.68 ± 0.32		
Published data	30	4.47 ± 0.52	3.43	5.51
Present study	40	4.71 ± 0.33		
Published data	40	4.51 ± 0.46	3.59	5.43
Present study	50	4.71 ± 0.30		
Published data	50	4.56 ± 0.37	3.82	5.30
Present study	60	4.74 ± 0.20		
Published data	60	4.55 ± 0.34	3.87	5.23
Present study	70	4.92 ± 0.18		
Published data	70	4.70 ± 0.33	4.04	5.36
Present study	80	4.99 ± 0.13		
Present study	80	4.68 ± 0.32		

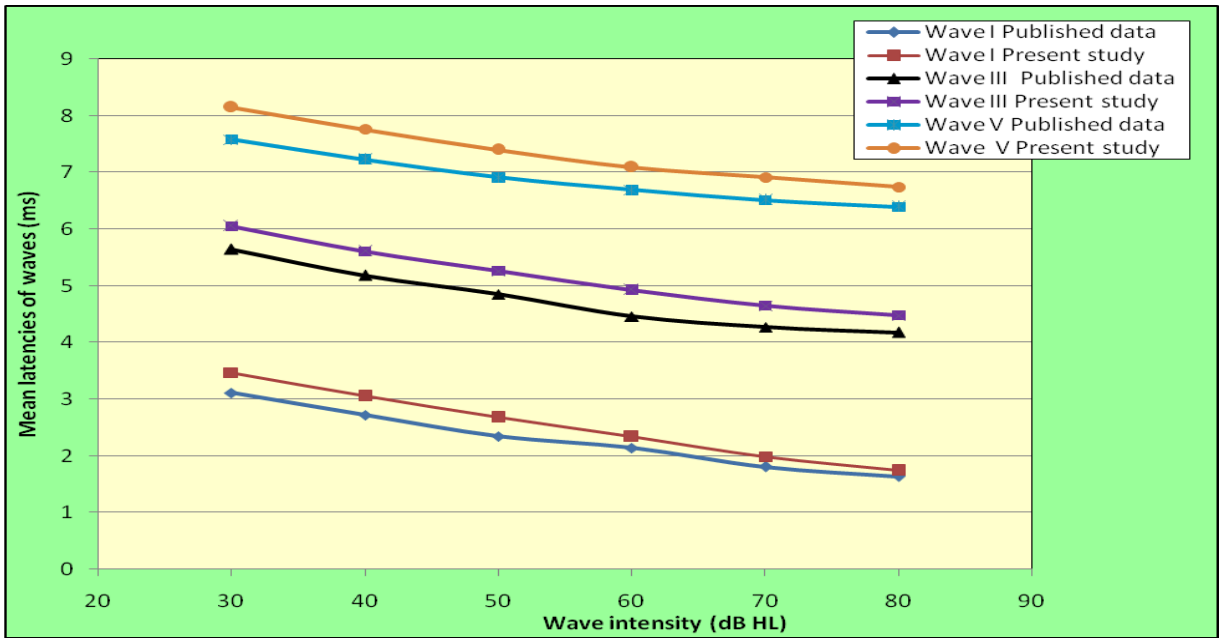

Figure 4.1: Comparative summary of absolute latencies of current study and IHS published data

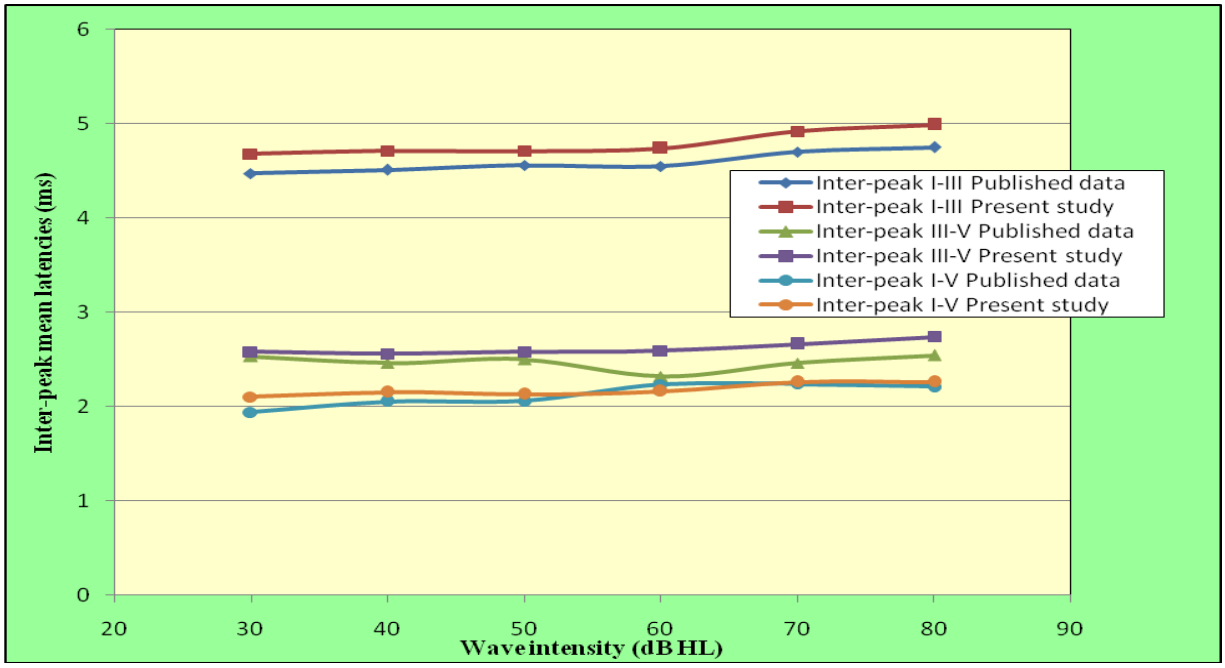

Figure 4.2: Comparative summary of the inter-peak latencies of current study and IHS published data

4.5 EFFECT OF GENDER ON MEAN LATENCIES

The *t*-statistic was employed to test the effect of gender on absolute and inter-peak mean latency values. The results are depicted in Tables 4.10 - 4.15.

Table 4.10: Effect of gender on click ABR latencies at test intensities: Peak I

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	3.47	0.28	-0.55	28	0.96
	Female	15	3.48	0.20			
40	Male	15	3.08	0.26	0.54		0.60
	Female	15	3.03	0.14			
50	Male	15	2.76	0.27	1.50		0.16
	Female	15	2.62	0.13			
60	Male	15	2.43	0.19	2.25		0.05
	Female	15	2.27	0.12			
70	Male	15	2.03	0.13	1.43		0.17
	Female	15	1.96	0.09			
80	Male	15	1.79	0.05	1.96		0.08
	Female	15	1.71	0.11			

α=0.05

Table 4.10 depicts a non-significant effect of gender on Peak I latencies at the respective test intensities [$t_{(28)}$ = -0.55, 0.54, 1.50, 2.25, 1.43, 1.96; p > 0.05]. This is evidenced in the non-significant difference between the mean latency values for males and females. The results of Table 4.11 showed no significant difference between male and female mean latency values for Peak III at the respective test intensities [$t_{(28)}$= 0.82, 1.87, 1.93, 1.90, 0.56, 0.39; $p > 0.05$]. This is evidenced in the non-significant difference between the mean latencies for males and females.

Table 4.11: Effect of gender on click ABR latencies at test intensities: Peak III

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	6.12	0.37	0.82	28	0.42
	Female	15	6.00	0.29			
40	Male	15	5.76	0.35	1.87		0.08
	Female	15	5.50	0.24			
50	Male	15	5.41	0.34	1.93		0.07
	Female	15	5.15	0.22			
60	Male	15	5.06	0.34	1.90		0.08
	Female	15	4.83	0.18			
70	Male	15	4.69	0.35	0.56		0.58
	Female	15	4.62	0.19			
80	Male	15	4.51	0.40	0.39		0.71
	Female	15	4.46	0.13			

α=0.05

Table 4.12: Effect of gender on click ABR latencies at test intensities: Peak V

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	8.31	0.27	2.51	28	0.02
	Female	15	8.02	0.21			
40	Male	15	7.95	0.31	2.76		0.01
	Female	15	7.62	0.20			
50	Male	15	7.57	0.28	2.93		0.01
	Female	15	7.26	0.16			
60	Male	15	7.22	0.20	2.71		0.02
	Female	15	6.98	0.18			
70	Male	15	6.99	0.20	1.70		0.11
	Female	15	6.85	0.15			
80	Male	15	6.78	0.13	1.28		0.22
	Female	15	6.70	0.14			

Table 4.12 revealed a significant difference between male and female mean latency values at 30, 40, 50, and 60 dBnHL [$t_{(28)}$= 2.51, 2.76, 2.93, 2.71; $p < 0.05$] and a non-significant mean difference at 70 and 80 dBnHL [$t_{(28)}$= 1.70, 1.28; $p > 0.05$] for Peak V. The respective mean differences are 0.29, 0.33, 0.31, 0.24, 0.14, and 0.08.

Table 4.13: Effect of gender on click ABR latencies at test intensities: Inter-peak I-III

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	2.65	0.31	0.99	28	0.34
	Female	15	2.52	0.27			
40	Male	15	2.68	0.30	1.88		0.08
	Female	15	2.47	0.15			
50	Male	15	2.64	0.31	0.96		0.35
	Female	15	2.53	0.22			
60	Male	15	2.63	0.22	0.77		0.45
	Female	15	2.56	0.20			
70	Male	15	2.66	0.38	-0.02		-0.00
	Female	15	2.67	0.19			
80	Male	15	2.72	0.43	-0.22		0.83
	Female	15	2.75	0.14			

α=0.05

From Table 4.13 there was no significant difference between male and female mean latency values at 30, 40, 50, 60 and 80 dB nHL [$t_{(28)}$= 0.99, 1.88, 0.96, 0.77 & -0.22; $p > 0.05$] respectively except at 70 dB nHL [$t_{(28)}$= -0.02, $p > 0.05$] for Inter-peak I-III. The respective mean differences are 0.13, 0.21, 0.11, 0.07, -0.01 and -0.03.

Table 4.14: Effect of gender on click ABR latency at test intensities: Inter-peak III-V

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	2.19	0.37	1.11	28	0.28
	Female	15	2.03	0.24			
40	Male	15	2.19	0.43	0.51		0.62
	Female	15	2.12	0.22			
50	Male	15	2.16	0.41	0.38		0.71
	Female	15	2.11	0.16			
60	Male	15	2.16	0.41	0.01		0.99
	Female	15	2.11	0.16			
70	Male	15	2.29	0.32	0.55		0.59
	Female	15	2.23	0.16			
80	Male	15	2.28	0.40	0.23		0.82
	Female	15	2.25	0.13			

Table 4.15 Effect of gender on click ABR at test intensities: Inter-peak I-V

Intensity (dBnHL)	Gender	N	Mean	SD	*t* (2-tailed)	*df*	*p-value*
30	Male	15	4.84	0.37	2.15	28	0.05
	Female	15	4.55	0.19			
40	Male	15	4.87	0.42	1.95		0.07
	Female	15	4.59	0.17			
50	Male	15	4.81	0.41	1.21		0.24
	Female	15	4.64	0.17			
60	Male	15	4.79	0.23	0.81		0.43
	Female	15	4.71	0.18			
70	Male	15	4.96	0.23	0.70		0.49
	Female	15	4.89	0.13			
80	Male	15	4.99	0.13	-0.02		0.99
	Female	15	5.00	0.14			

α=0.05

Table 4.14 showed a non-significant difference between male and female mean value for Inter-peak III-V latency values at the respective test intensities [$t_{(28)}$= 1.11, 0.51, 0.38, 0.01, 0.55, 0.23; $p > 0.05$]. The respective mean differences are 0.16, 0.07, 0.05, 0.05, 0.06 and 0.03.

Table 4.15 showed a non-significant difference between male and female mean values for inter-peak V-I latencies at the respective test intensities [$t_{(28)}$ = 2.15, 1.95, 1.21, 0.81, 0.70, -0.02; p > 0.05].The respective mean differences are 0.29, 0.28, 0.17, 0.08, 0.07 and -0.01.

CHAPTER FIVE

DISCUSSION OF RESULTS

5.1 INTRODUCTION

The results of this study are discussed in this Chapter. The discussion is categorized into demographic variables, testing of hypothesis one and testing of hypothesis two.

5.2 DEMOGRAPHIC VARIABLES

Out of a total of 50 subjects, 50% were males and the remaining 50% were females. Participants were within the age range of 2-8 weeks. Sininger (1992) suggested that a minimum of 10 females and 10 males who have normal hearing and no history of ear or hearing related disorders should be utilized in building ABR normative data.

5.3 TESTING OF HYPOTHESIS 1

H_1: There will be no significant clinical difference between the clinically developed normative values and the IHS published normative values for waves I, III, V and inter-peak I-III, III-V and I-V latencies.

The first hypothesis was supported by the data collected. This means that the results from the 30 participants for absolute and inter-peak latencies fell within 2 SD of the published normative data at all the tested intensities. Although all the latencies for waves I, III, V and inter-peaks I-III, III-V, I-V were delayed, they were within allowable limits for norm acceptability. Waves I, III and V delayed by 0.10, 0.30 and 0.35 ms at 80 dBnHL respectively and by 0.36, 0.41 and 0.57 ms at 30 dBnHL respectively while inter-peaks I-III, III-V, I-V also delayed by 0.20, 0.05 and 0.24 ms

respectively at 80 dBnHL and by 0.05, 0.16 and 0.21 ms at 30 dBnHL respectively. Observably, average latency delay increased steadily across waves I, III and V while the sum of mean latencies at each test intensity of inter-peaks I-III and III-V approximated the mean latencies of inter-peak I-V at the respective test intensities. This finding is consistent with a study by Laura, Guilhoto, Quintal and Da Costa (2013) which researched into ABR latencies on 47 neonates using 80 dBnHL clicks of alternating polarity at a rate of 10/second and recorded increase in latency values. In the same vein, Costa, Aurelio, Braz and Rodrigues (2014) recorded an increase in absolute and inter-peak latency values for neonates.

The non-significant delays in the absolute and inter-peak latencies can be explained by tester, environmental and test protocol settings variability. For example, the filter settings used in the current study varied from the setting utilized in generating the published normative data. According to Sininger (1995) filtering is used in evoked-potential measurements to reduce background noise to suppress unwanted spectral components without altering neural activity. In ABR measurement, filters reject electrical energy at certain frequencies and pass energy at other frequencies. Sininger (1995) concluded that filter choice could affect the efficiency of ABR measurement. In a similar study, Diao et al., (2011) compared the thresholds of click and tone burst ABR with two different filter settings (30 - 1500 Hz and 30 - 3000 Hz). Results from the study indicated that, thresholds of tone burst ABR with filter settings of 30 - 3000 Hz were higher than that with filter settings of 30 - 1500 Hz. Furthermore, Sanchez and Gans (2006) concluded that noise had a detrimental effect on waveform morphology of the ABR that could lead to difficulty in ABR interpretation.

Marcoux and Kurtz (2012) asserted that, muscular activity from newborns produce significant artifact that may interfere with the ABR. This is always present in non-relaxed neonates and normally disappears as the subject sleeps particularly under sedation (Sokolov et al., 2005). Again, Bridger and Graham (1985) recorded a significant latency difference as a result of raised body temperature on ABRs in nine neonates with normal hearing.

In a similar study, Rodriguez et al., (1999) examined the effects of temperature on ABR in neonates and recorded significant increases and decreases with cooling in ABR latencies and amplitudes respectively. Additionally, Arnold (2007) reported that decrease in body temperature below 36 degree Celsius causes an increase in ABR inter-peak latency. This effect results in slowed neural conduction velocity and synaptic transmission. Arnold (2007) subsequently suggested temperature measurements prior to ABR evaluation in newborns with low birth weight since they are prone to hypothermia. According to Jacobson and Hall (1994), effects of decreasing body temperature (36°C) will prolong absolute and relative latency and decrease response amplitude.

In conclusion, there was a non-clinical-significant difference between the clinically developed normative values for waves I, III, V and inter-peak I-III, I-V and III-V latencies and the IHS published normative values though the clinical established norm of the study showed some delays across the test intensities.

5.4 TESTING OF HYPOTHESIS 2

$H_{2:}$ Gender will have no significant effect on absolute and inter-peak mean latencies at all tested intensities.

The present study showed statistically significant effect of gender on mean absolute latencies for Wave V at 30, 40, 50 60 dBnHL and also on inter-peak I-III at 70 dBnHL. However, there was no significant effect of gender on all other tested absolute and inter-peak mean latencies. Comparing the outcome of the current study with other similar studies, Romero, et al., (2012) investigated the auditory behavior of 41 infants aged 1 to 9 months through the ABR and found no influence of gender on the latencies. However, according to Angrisani, et al., (2012) there are few studies that sought to determine the influence of gender on the ABR results in newborns.

In a related study, Angrisani et al., (2012) concluded that gender exerts significant influence on the ABR of full term newborns with shorter responses in females. Thus, the literature reports conflicting results on the effect of gender on ABR latencies for neonates. In conclusion, the argument on the effect of gender on ABR latencies for neonates may be resolved by approaching the subject with emphasis on test protocol differences, tester and participant biases and environmental conditions.

5.5 LIMITATION TO THE STUDY

The results of this study depicted an inconsistent statistical significant effect of sex on ABR latencies at the tested intensities. Therefore, sex may affect ABR interpretation for the tested age group and clinicians should consider them in clinical settings.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 INTRODUCTION

A summary of the research findings, conclusions and appropriate recommendations drawn from the study are presented in this Chapter.

6.2 SUMMARY OF THE STUDY

The study aimed at developing a clinical normative data for neonates using ABR to ensure objective and valid interpretation of ABR test of neonates at Korle-Bu Teaching Hospital. The objectives of the study included:

- How the norms established by the study will compare with the published norms.
- The effect of gender on the ABR latencies of neonates.

The major findings of the study revealed that:

- The absolute and inter-peak mean latencies for the normative data established by the present study were within 2 SD of the published data.
- The present study showed statistically significant effect of gender on mean absolute latencies for wave V at 30, 40, 50 60 dBnHL and also on inter-peak I-III at 70 dBnHL. However, there was no significant effect of gender on all other tested absolute and inter-peak mean latencies.

6.3 CONCLUSION

The results from the study are appropriate and should be used for screening purposes at KBTH Hearing Assessment Centre.

6.4 RECOMMENDATIONS

Based on the findings of the study, the following recommendations were made:

- The clinically established normative data by the study are appropriate and should be used for screening neonates at the KBTH Hearing Assessment Centre
- It is further recommended that a determination of the latency values and amplitude ratios for pre-term babies at the KBTH HAC should be established to enhance the diagnostic ability of the clinician.

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APPENDICES

APPENDIX I

PARTICIPANT INFORMATION FORM

Department of Audiology

Title of research: Developing Clinical Normative Data for Neonates using Auditory Brainstem Response at Korle-Bu Teaching Hospital

Study procedure

Participants visiting the KBTH Hearing Assessment Center for Universal Newborn Hearing Screening (UNHS) will be recruited for the study. Data collection sheet will be given to participants to fill the demographic data after which Auditory brainstem response audiometry will be recorded by monaural presentation.

Risk to the patient

There are minimal risks for participation in this study since the testing equipment and procedure does not give any side effect.

Possible Benefits

Participating in the study provides you with the opportunity of knowing your baby's hearing status.

Confidentiality

All information provided will remain confidential and will only be reported as group data with no identifying information. All data, including test results will be kept in a secure location and only those directly involved with the research will have access to them.

Compensation

Participants who commute to have the testing done will have their transportation fares catered for.

Your rights as a Participant

This research has been reviewed and approved by the Ethics and Protocol Committee of the School of Allied Health Sciences, College of Health Sciences, University of Ghana. If you have any questions about your rights as a research participant you can contact the Ethics and Protocol Committee Office.

APPENDIX II

PARTICIPANT INFORMED CONSENT FORM

DEPARTMENT OF AUDIOLOGY

SCHOOL OF BOIMEDICAL AND ALLIED HEALTH SCIENCES

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

TITLE OF PROJECT: DEVELOPING CLINICAL NORMATIVE DATA FOR NEONATES USING AUDITORY BRAINSTEM RESPONSE AT KORLE-BU TEACHING HOSPITAL

NAME OF RESEARCHER: FRANKLIN AKUAMOAH

CONFIDENTIALITY: All data will be confidentially and anonymously handled. At any stage of the research, you have right to opt out.

I ……. agree to take part in the above research and I consent to my participation. The purpose of the research has been explained and I understand also that my participation is entirely voluntary and that there is no personal benefit that I will derive by participating in the study. If you have any concerns about this study and wish to contact someone independently, you may contact the Programme Coordinator Dr. S. Anim-Sampong (020777400).

ABSOLUTE WAVE LATENCIES AT 30, 40 and 50 dBnHL

IDENTITY	I	III	V	I	III	V	I	III	V
AAF	3.05	5.45	7.55	2.65	5.10	7.40	2.40	4.85	7.00
AAM	3.10	5.50	7.85	2.75	5.25	7.55	2.45	4.90	7.10
EA	3.20	5.75	7.95	2.85	5.30	7.60	2.60	4.95	7.15
MAMA	3.25	5.80	8.05	2.90	5.40	7.65	2.65	5.00	7.20
WE	3.30	5.85	8.10	2.95	5.45	7.70	2.70	5.10	7.30
HO	3.35	5.90	8.15	3.00	5.60	7.75	2.75	5.15	7.40
PAM	3.50	6.00	8.20	3.05	5.65	7.80	2.80	5.25	7.55
RS	3.55	6.05	8.30	3.10	5.75	7.85	2.90	5.30	7.60
GF	3.60	6.10	8.35	3.15	5.80	7.90	3.05	5.40	7.70
RBA	3.65	6.25	8.50	3.20	5.85	7.95	3.20	5.55	7.75
BKAD	3.70	6.35	8.60	3.30	5.90	8.05	2.80	5.65	7.95
RAA	3.75	6.45	8.65	3.45	6.10	8.10	3.05	6.05	7.70
KA	3.85	6.65	8.60	3.45	6.25	8.25	2.75	5.65	7.60

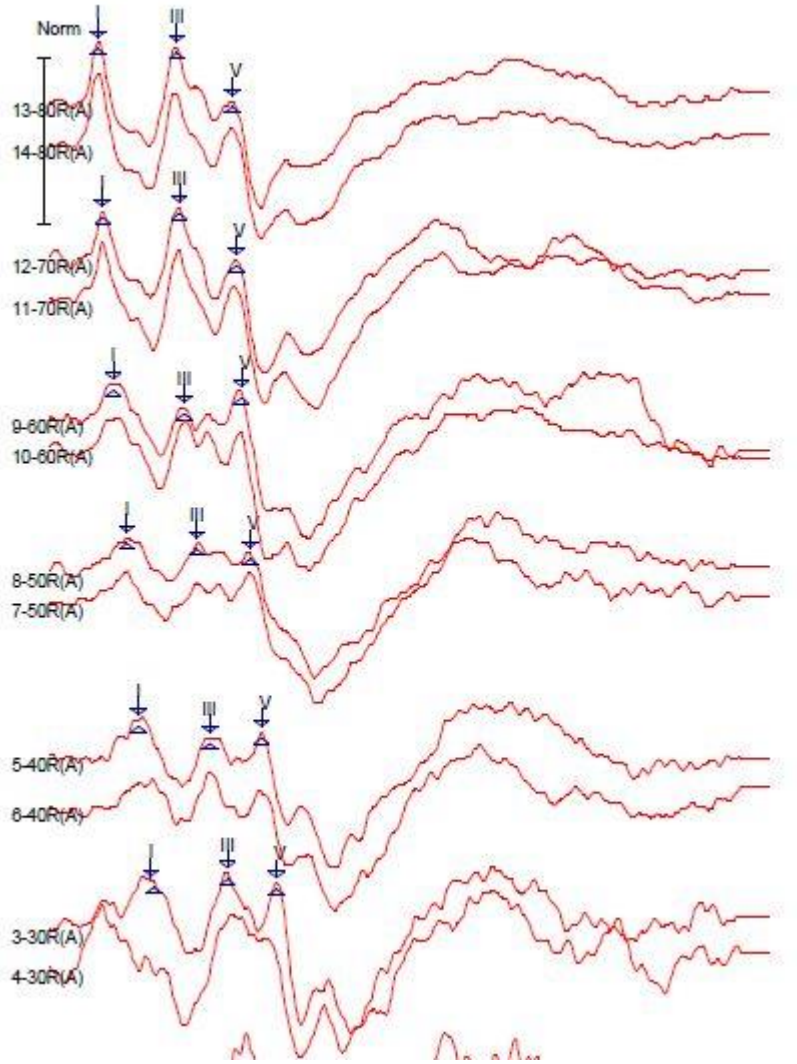
ABSOLUTE WAVE LATENCIES AT 60, 70 and 80 dBnHL

IDENTITY	I	III	V	I	III	V	I	III	V
AAF	2.05	4.55	6.70	1.80	4.20	6.55	1.50	3.80	6.45
AAM	2.15	4.60	6.85	1.85	4.25	6.65	1.60	4.10	6.55
EA	2.30	4.70	6.90	1.90	4.30	6.70	1.70	4.25	6.60
MAMA	2.35	4.75	7.00	1.95	4.40	6.80	1.75	4.30	6.65
WE	2.40	4.80	7.05	2.00	4.45	6.85	1.80	4.35	6.70
HO	2.55	4.85	7.10	2.05	4.50	6.90	1.85	4.40	6.80
PAM	2.65	4.95	7.15	2.10	4.65	6.95	1.75	4.45	6.85
RS	2.70	5.15	7.20	2.15	4.70	7.05	1.80	4.50	6.95
GF	2.05	5.30	7.25	2.20	4.75	7.00	1.65	4.55	6.70
RBA	2.15	5.40	7.35	2.15	4.80	7.20	1.55	4.60	6.65
BKAD	2.35	5.55	7.50	2.10	4.90	7.25	1.50	4.70	6.55
RAA	2.70	5.30	7.20	2.05	4.95	7.00	1.55	4.80	6.45
KA	2.40	5.15	7.25	1.85	5.05	7.05	1.70	4.85	6.55

APPENDIX III

SAMPLED RAW SCORES OF ABR RECORDINGS FROM PARTICIPANTS

CODE: AAF



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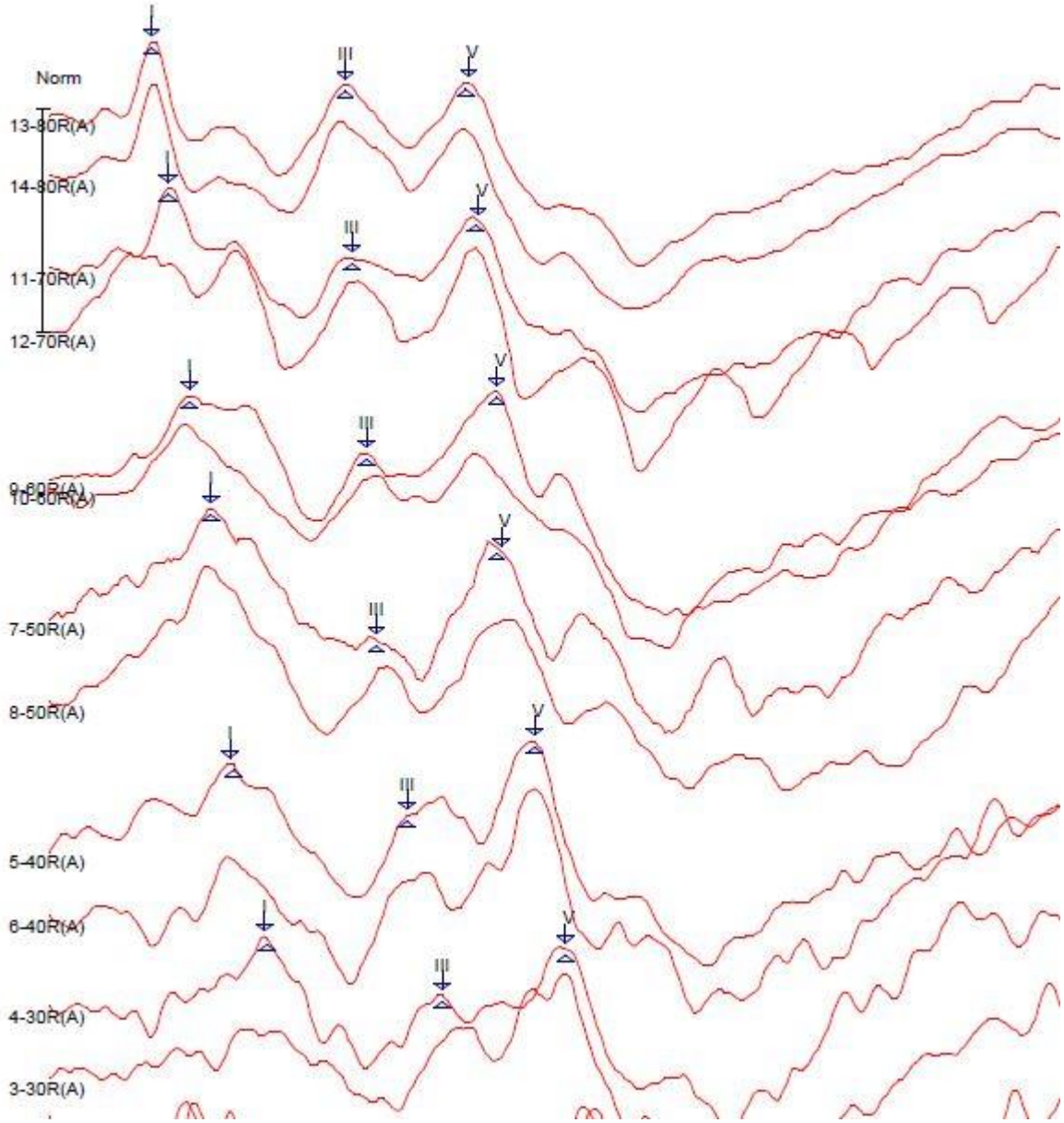

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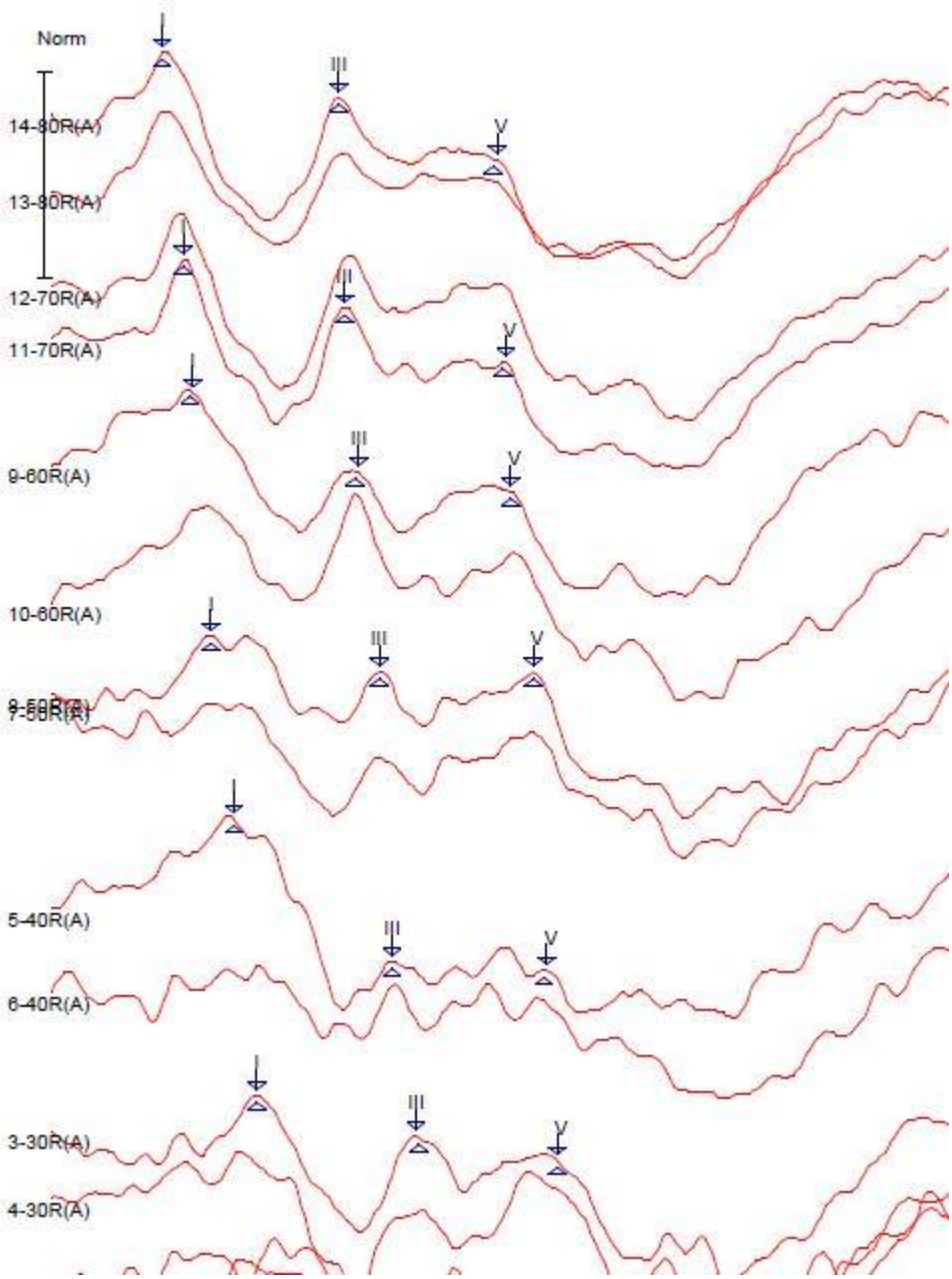

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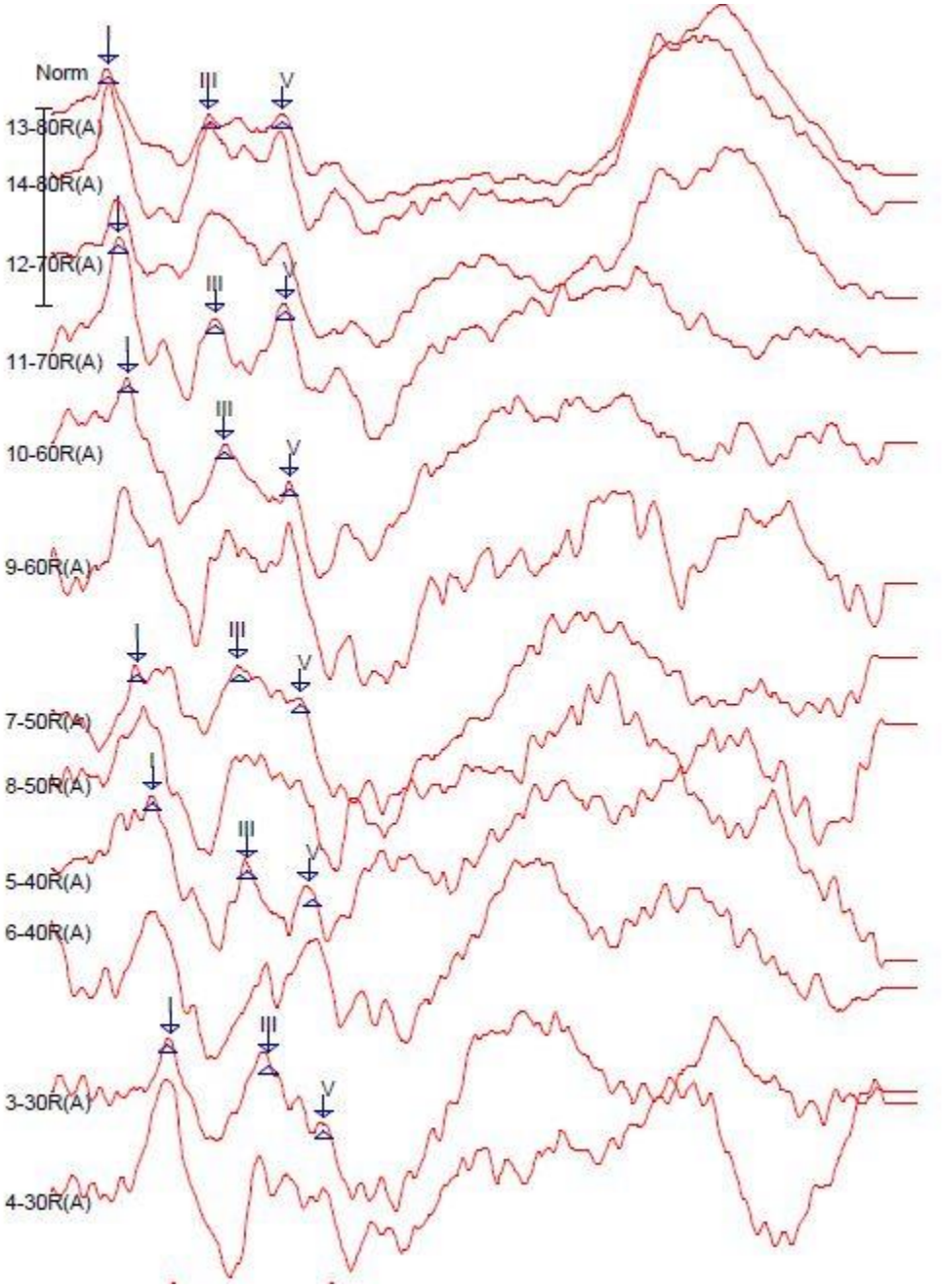

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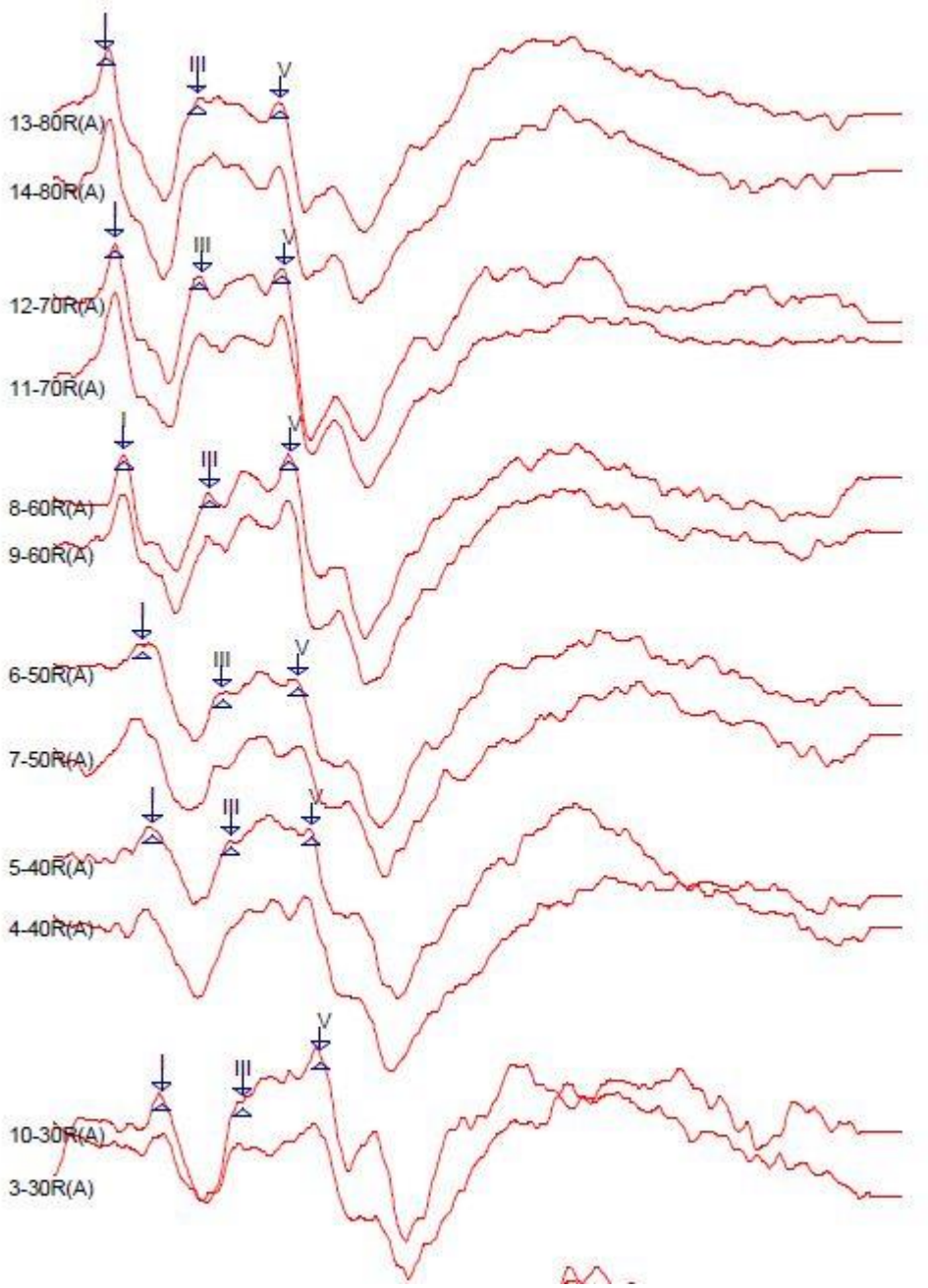
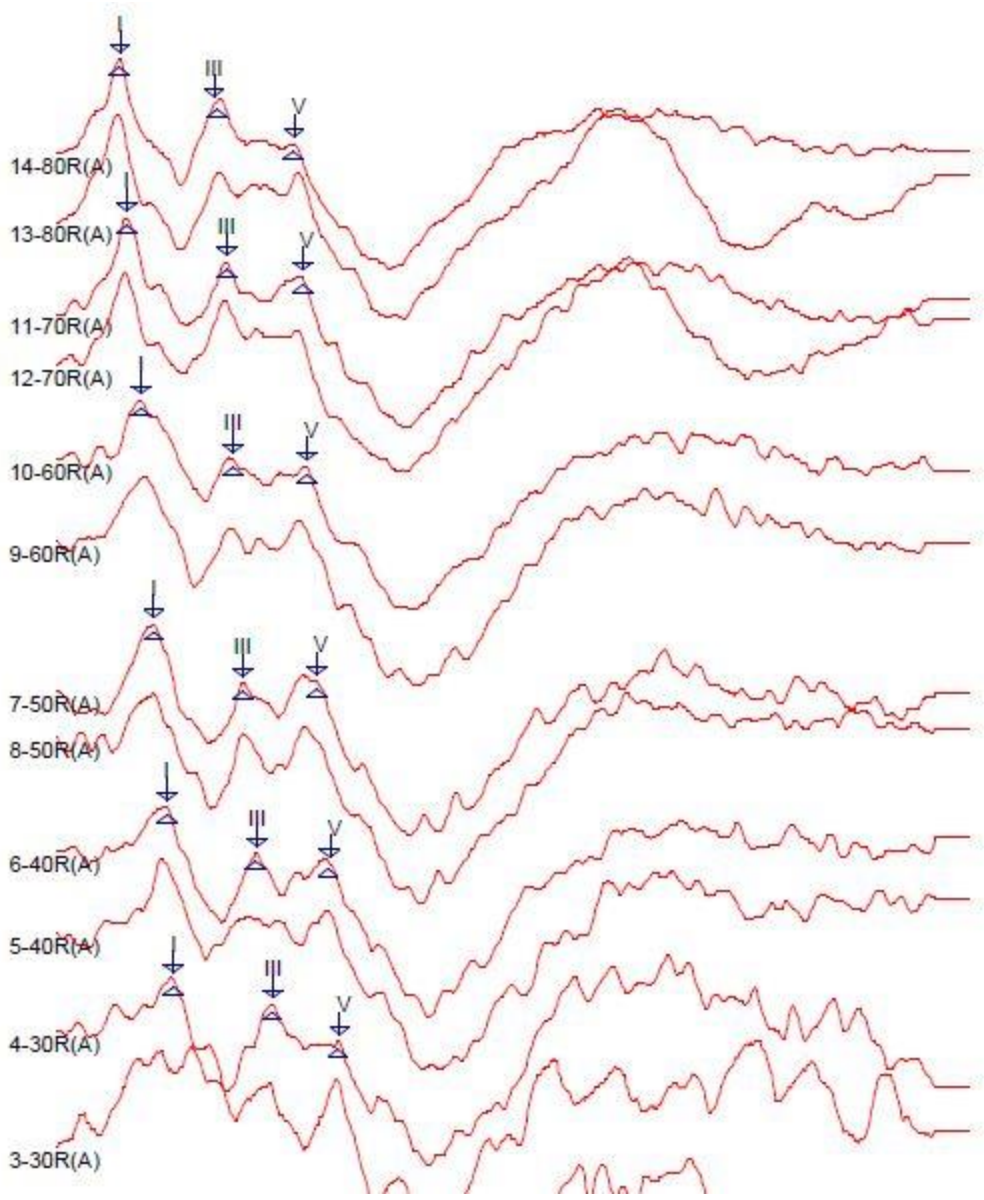


CODE: HO



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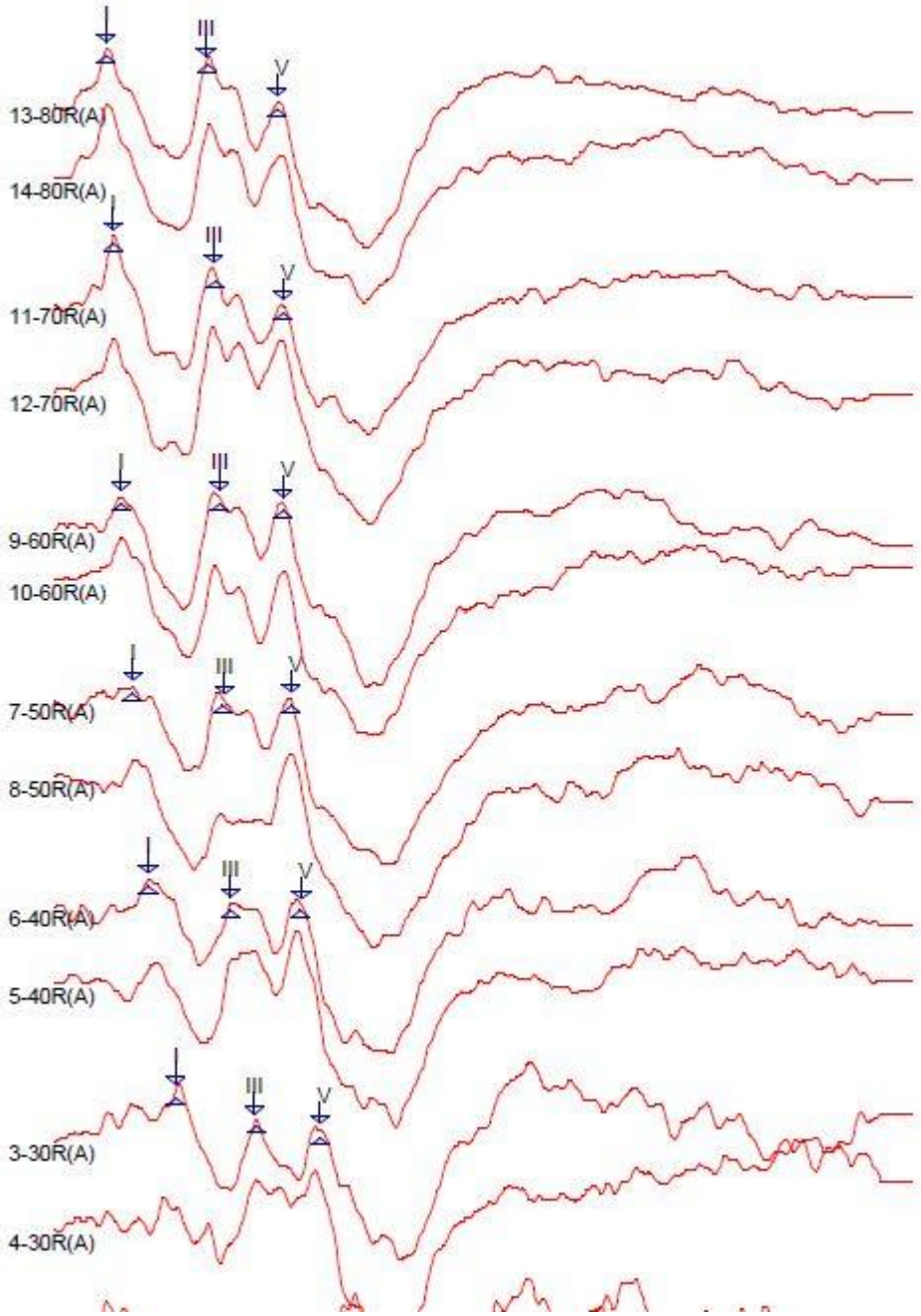

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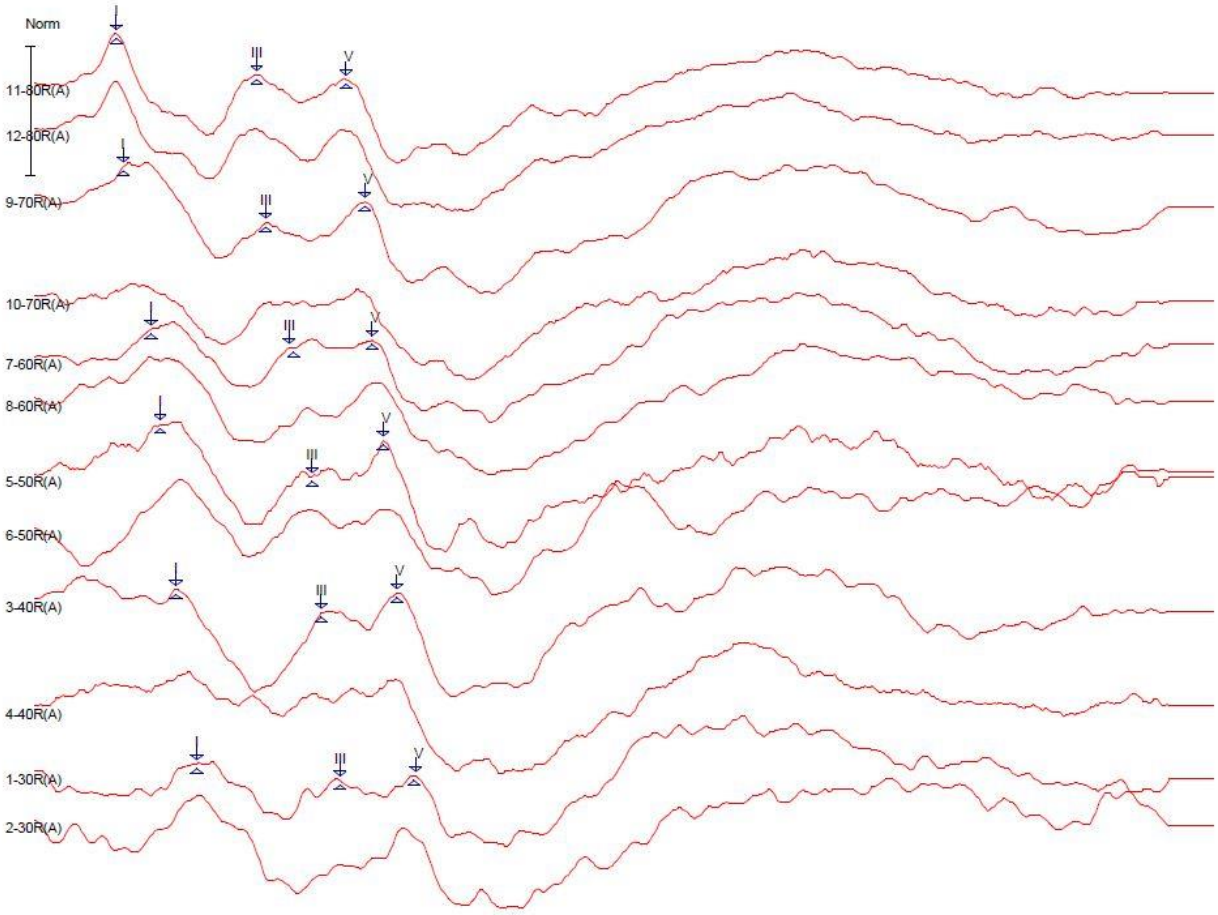

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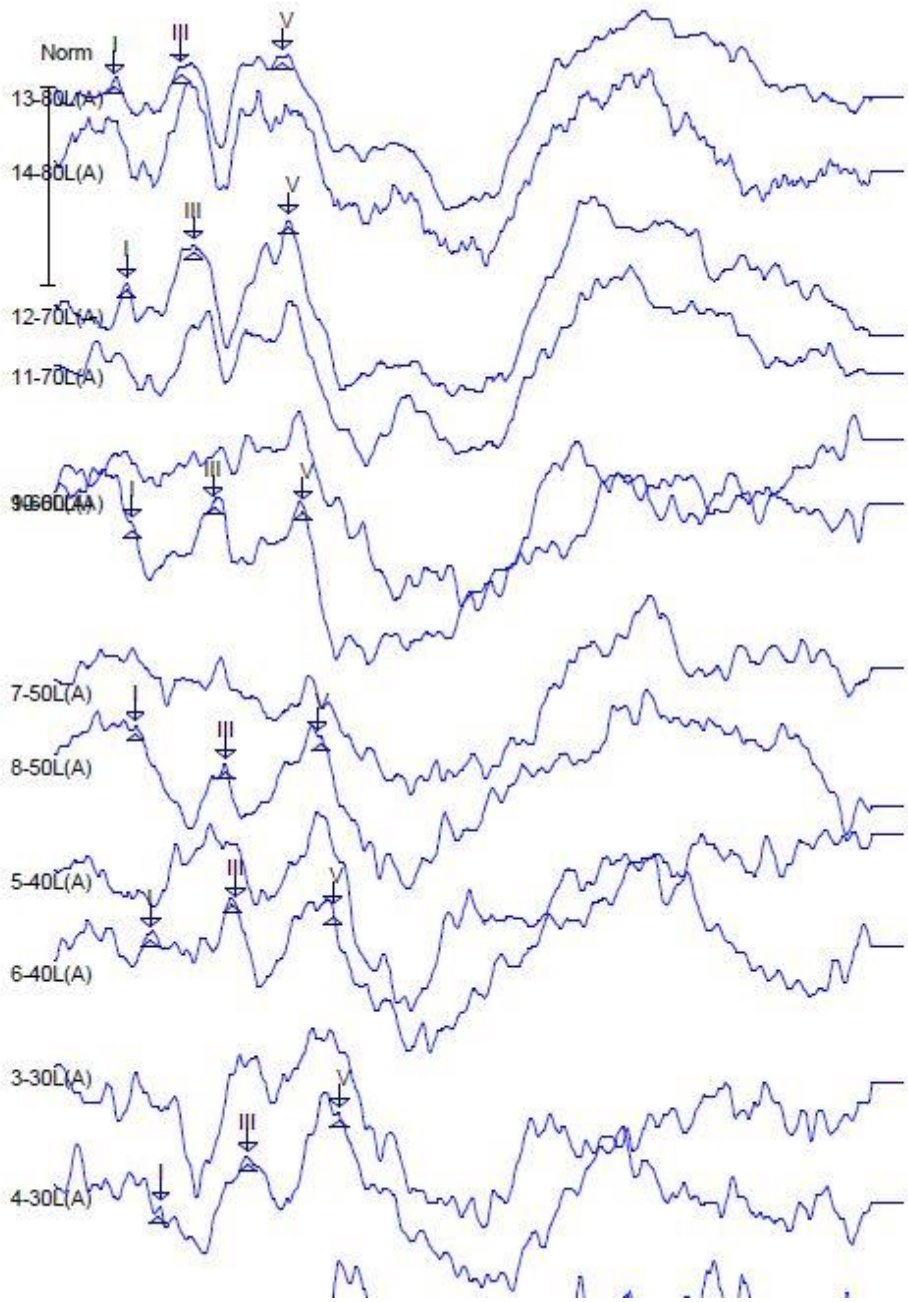

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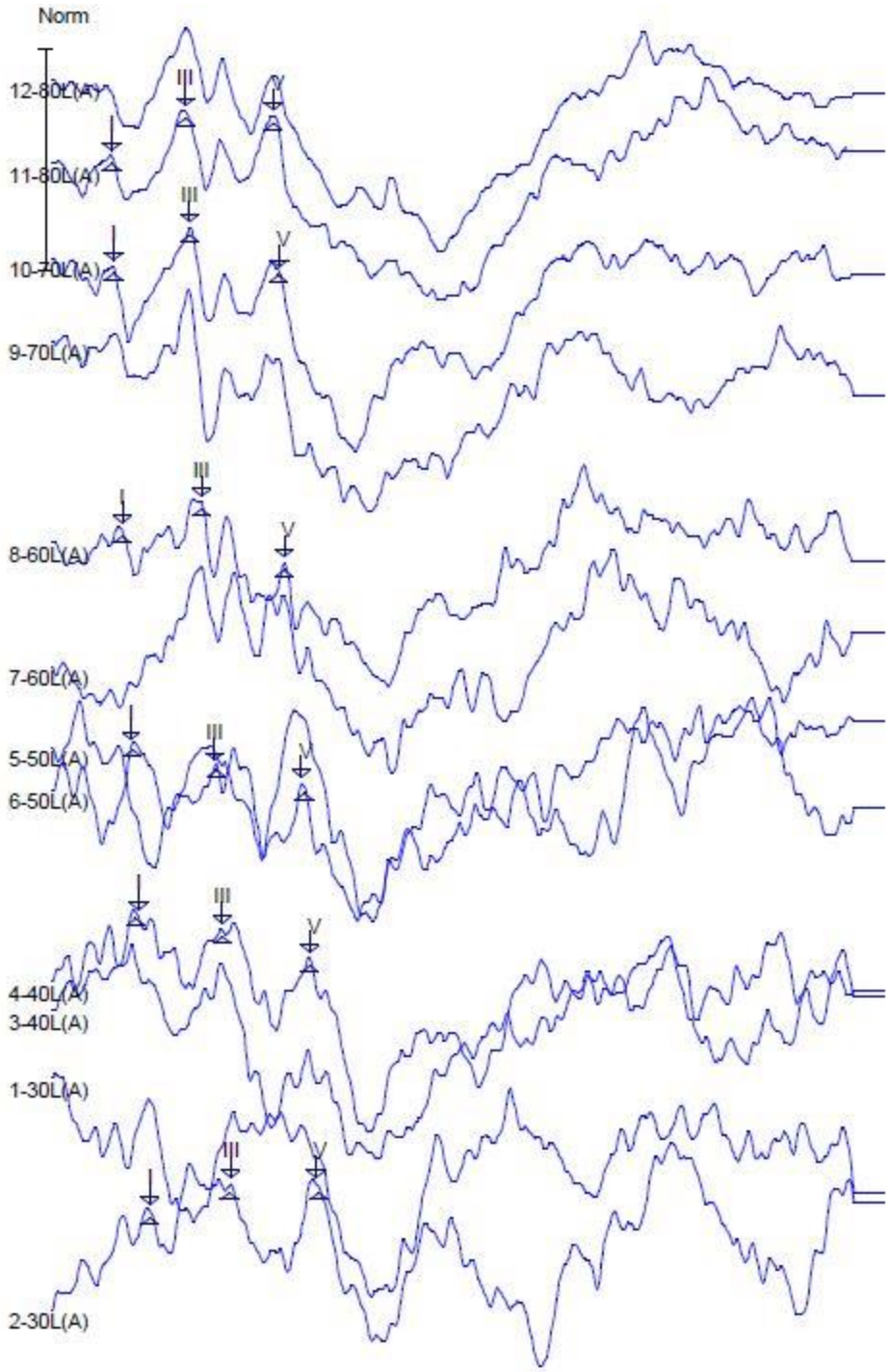

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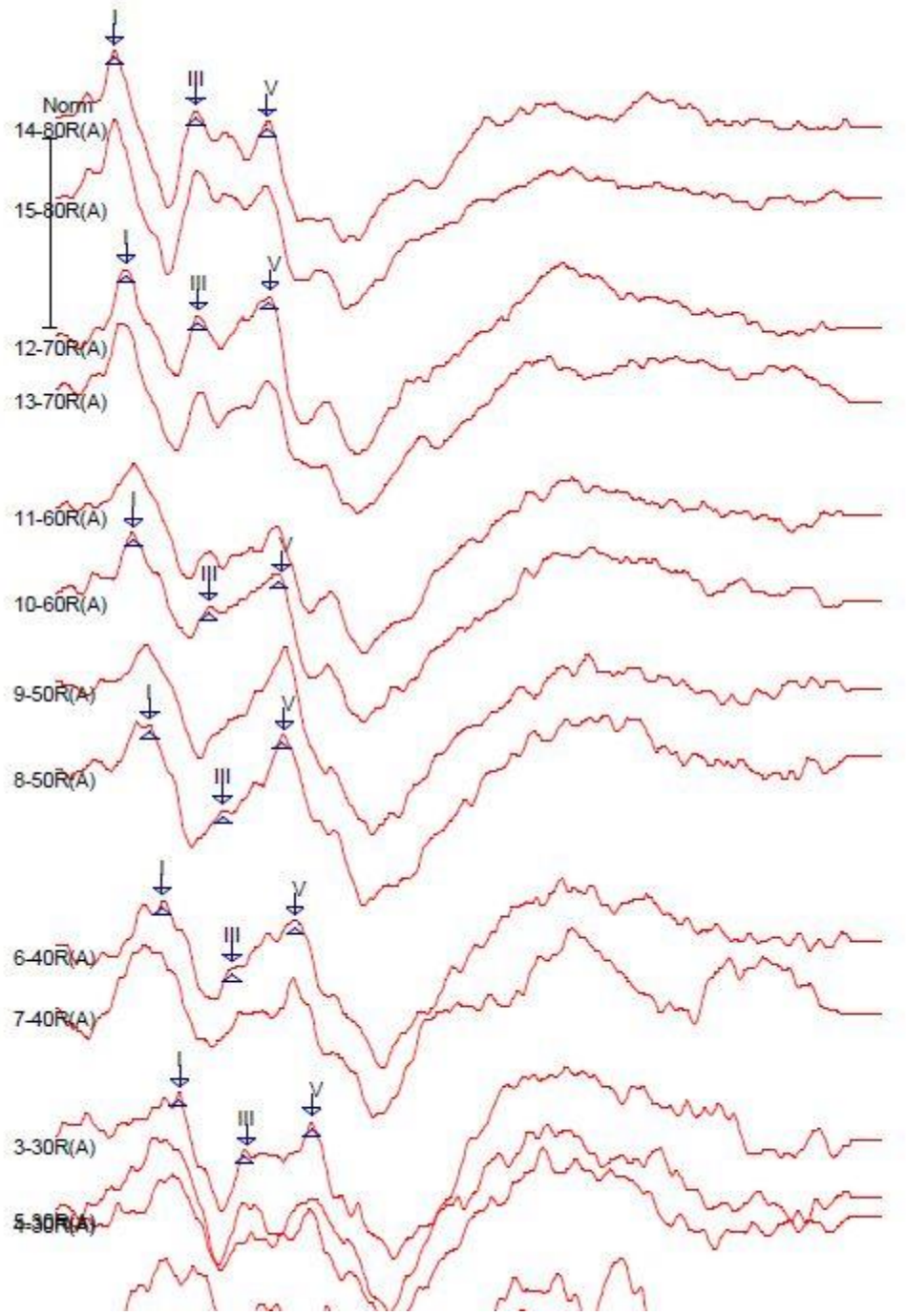

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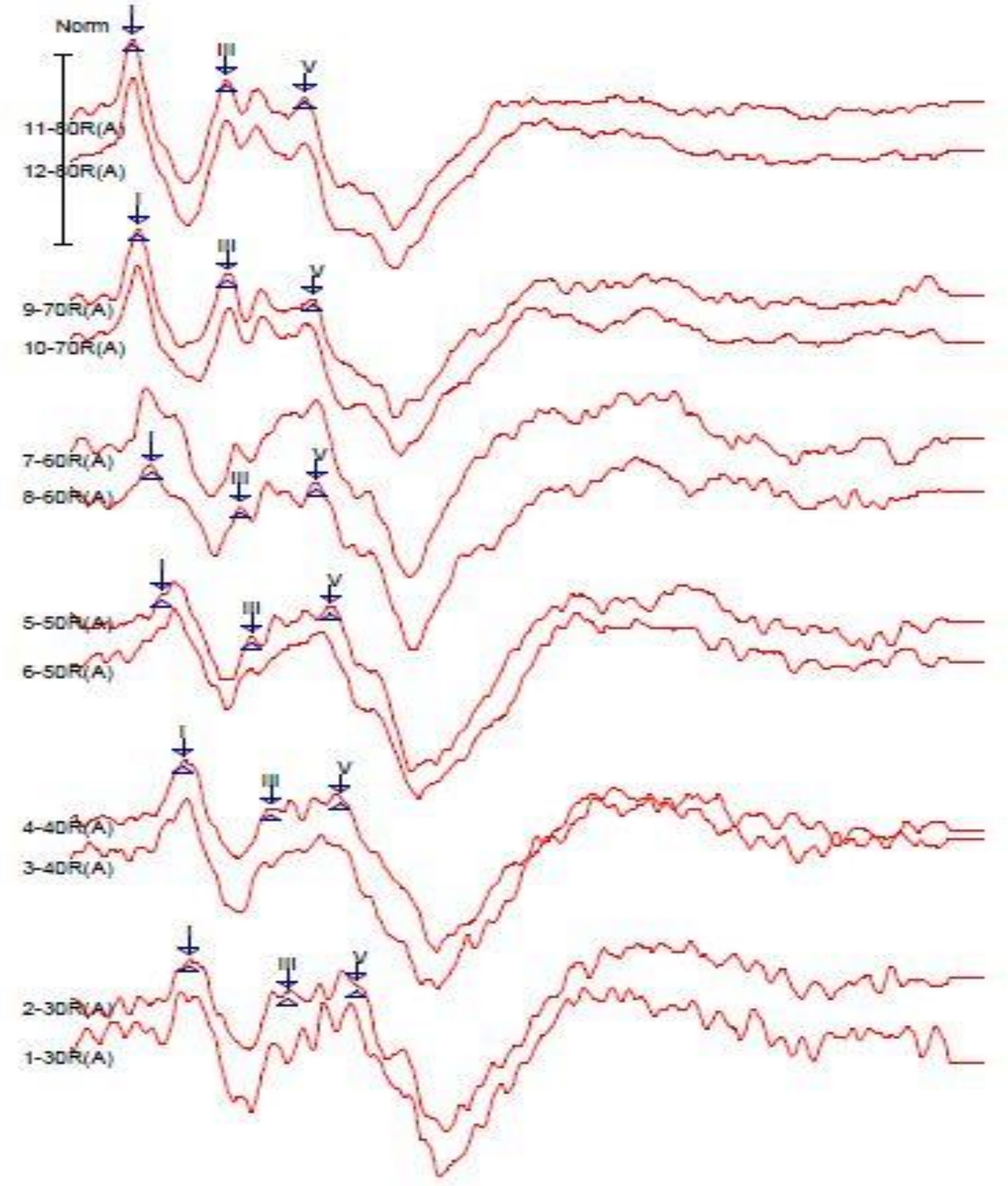

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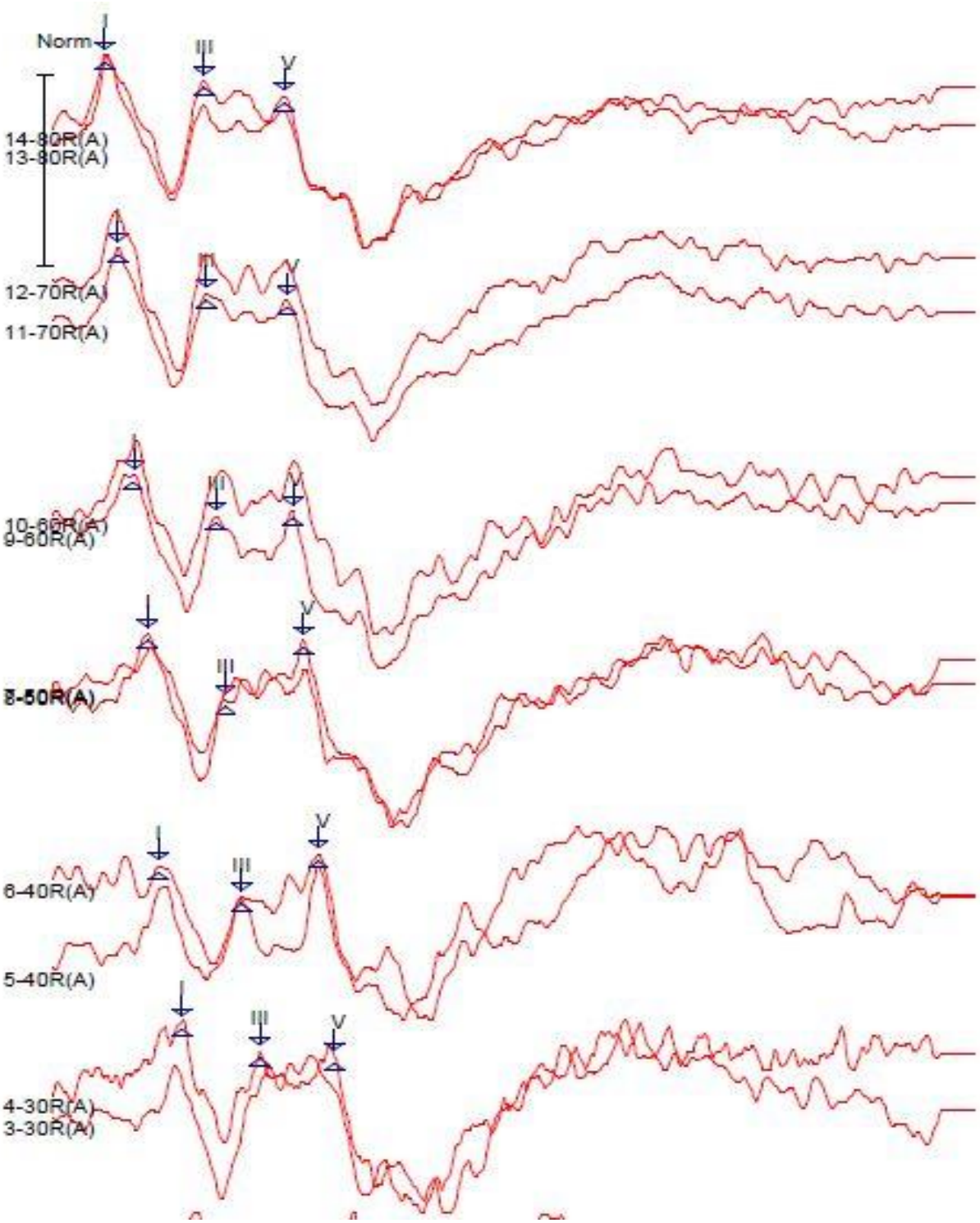

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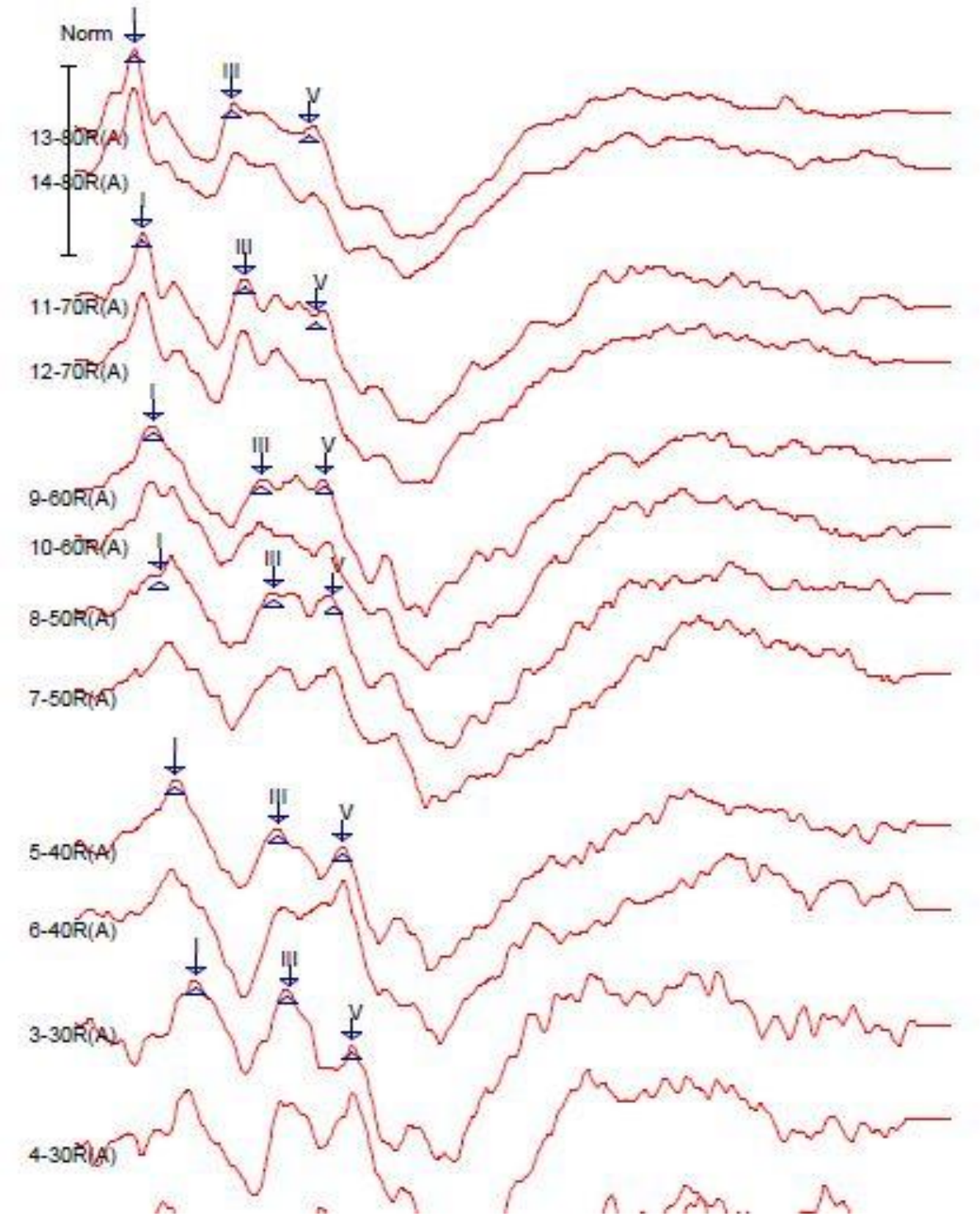

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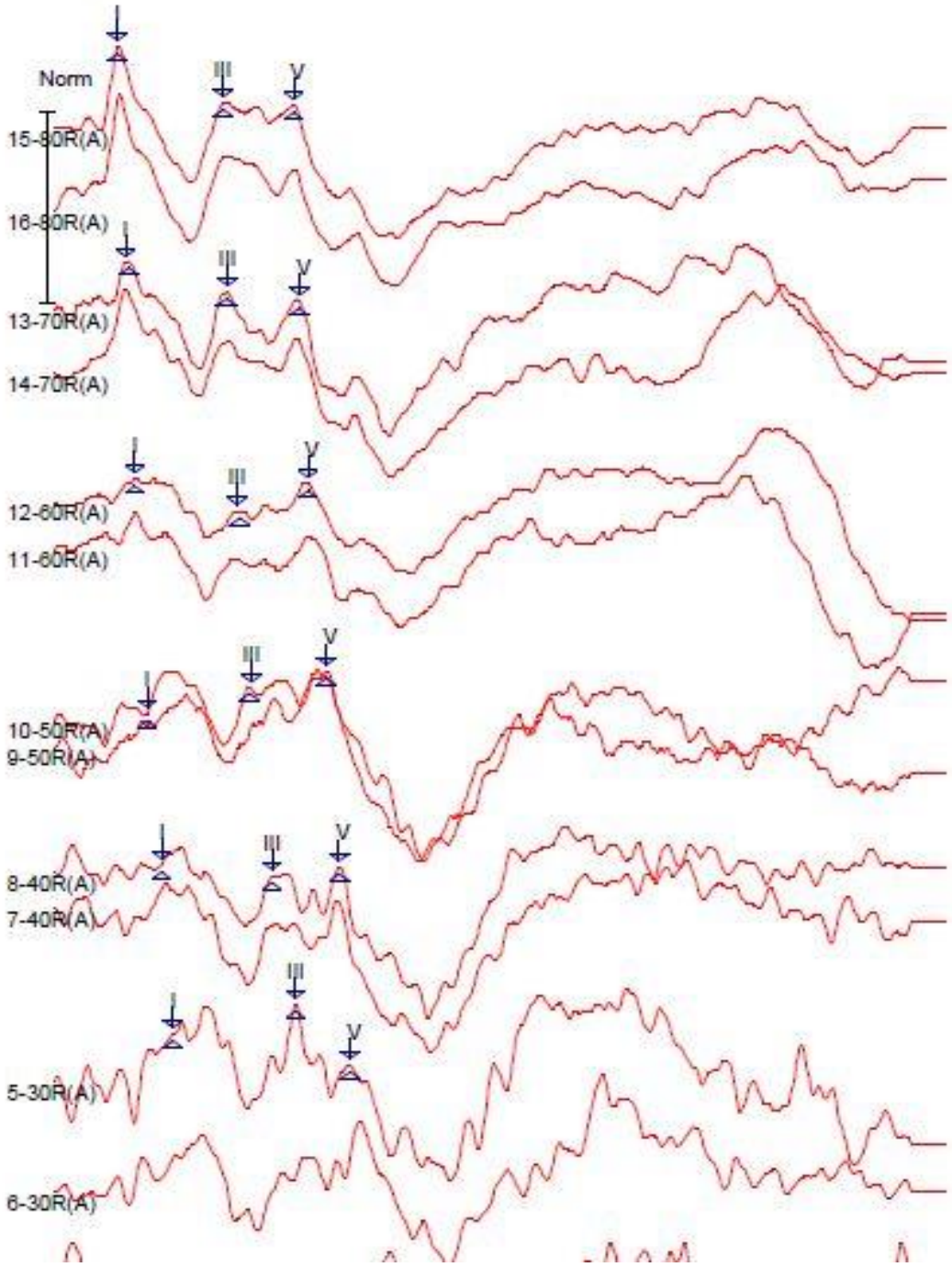

UNIVERSITY OF GHANA
SCHOOL OF BIOMEDICAL AND ALLIED HEALTH SCIENCES
DEPARTMENT OF AUDIOLOGY, SPEECH AND LANGUAGE THERAPY

October 7, 2014

Mr. Franklin Akuamoah
Dept. of Audiology, Speech and Language Therapy
SBAHS,
Korle Bu

Dear Franklin Akuamoah

ETHICS CLEARANCE

Following a technical and professional review of your research proposal by the Department Ethics and Protocol Review Committee and by your supervisors, I am pleased to inform you of the Committee's approval your research proposal entitled:

"Developing Clinical Normative Data for Neonates Using Auditory Brainstem Response at Korle Bu Teaching Hospital ".

This is an initial approval. You are therefore required to obtain a final approval from the School's Ethics and Protocol Review Committee per the Schools regulations.

You are required to work closely and in collaboration with your supervisors. Please report all serious adverse events related to this research to the supervisors and this Committee in writing.

Thank you.

Yours sincerely,

DR. S. ANIM-SAMPONG

For: Chairman DASL&T Ethics and Protocol Review Committee

DEPARTMENT OF AUDIOLOGY
SPEECH & LANGUAGE THERAPY
SCHOOL OF BIOMEDICAL AND ALLIED
HEALTH SCIENCES

UNIVERSITY OF GHANA
SCHOOL OF BIOMEDICAL AND ALLIED HEALTH SCIENCES
DEPARTMENT OF AUDIOLOGY, SPEECH AND LANGUAGE THERAPY

November 3, 2014

The Head
Hearing Assessment Centre
ENT Department
Korle Bu Teaching Hospital

Dear Sir/Madam,

PERMISSION TO CARRY MSc AUDIOLOGY RESEARCH PROJECT AT THE HEARING ASSESSMENT CENTRE, KBTH

The Department of Audiology, Speech & Language Therapy (DAS&LT) of the University of Ghana School of Biomedical and Allied Health Sciences (SBAHS) presents its compliments to you and has the pleasure requesting your kind consideration of the above subject.

Mr. Franklin Akuamoah is a 2nd year MSc Audiology student of the Department of Audiology, Speech and Language Therapy of SBAHS, University of Ghana. He is conducting a research project in "Developing Clinical Normative Data For Neonates Using Auditory Brainstem Response at Korle Bu Teaching Hospital" under the supervision of Dr. N. Boafo (Clinical Audiologist), and Dr. S. Anim-Sampong. His research study has been reviewed and passed by the Department's Ethics and Protocols Review Group of the School as meeting all ethical requirements.

The Department would be most grateful if you could kindly grant him permission to carry out this important research project for the common good of the University and your Centre. Thank you.

Yours faithfully,

Dr. S. ANIM-SAMPONG
For: (Head of Department)
cc: Dean (SBAHS)
Dr. N. Boafo

HEARING ASSESSMENT CENTRE

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

My Ref. No......
Your Ref. No......

KORLE BU TEACHING HOSP.
P.O. BOX 77
KORLE BU, ACCRA

Tel: 233-21- 673033-6
Fax: 233-21- 667759
Email: korlebu@ghana.com
Web Site: www.korlebu.com

17th November, 2014

The Head
Dept. of Audiology, Speech and Language Therapy
School of Biomedical and Allied Health Sciences
College of Health Sciences
University of Ghana

Dear Sir,

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

Permission has been granted Mr. Franklin Akuamoah to carry out a research project on "Developing Clinical Normative Data For Neonates Using Auditory Brainstem Response At Korle Bu Teaching Hospital".

He is expected to work closely with the Audiologist in charge to ensure safety of neonates and equipment used.

Yours Sincerely,

E. N. T. CLINIC
KORLE BU TEACHING HOSPITAL

JEMIMA A. FYNN (MRS.) FWACN
MSc. AUDIOLOGICAL SCIENCE

Cc: Head, ENT UNIT