

# HEARLab: bringing hearing to infants

First Edition



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This paper introduces “cortical” measurements and employs case studies to suggest ways to use “cortical” measurements to fit hearing aids and improve hearing aid outcomes for people who are difficult to test. The short DVD “The NAL HEARLab,” by Frye Electronics, Inc., shows the HEARLab system being used. The HEARLab NAL-ACA reference guide is a step-by-step set of instructions on how to operate the HEARLab machine.

## Introduction

We are very excited about this topic! It is great fun! The clinical use of cortical measurements will revolutionize how hearing tests and hearing aid fittings are done on infants and people who cannot or will not cooperate with the hearing tests. We want this paper to be a joy to read. So rather than talking about the “machine” we want to talk about infants and the experience their families have with hearing loss.

This paper begins with the story of Dr. Judy Smith, an audiologist, and two of her tiny patients: sweet Suzy and precious Danny. These infants and this doctor are not “real” people; they are inventions of the authors. Numerous case studies have been pulled together into this story, *a story of bringing hearing to infants*. This paper ends with the stories of John Doe and Tiffany; two complicated patients.

This is not a scientific paper. These are fun stories about a new clinical tool.

The profession of Audiology has changed each time a new diagnostic tool has been integrated into clinical practice. Audiologists have assimilated ABR, real ear, and tympanometry into their clinical armamentarium. We believe Audiology is about to take another step forward as *cortical measurements* are rediscovered and become another standard, very useful diagnostic test.

Our professional language is jam packed with hundreds, perhaps thousands of technical terms on evoked responses. It is hard to keep track of all of the terms. We will take big liberties with the technical language and talk about “cortical” curves or “cortical” responses—please remember this is a fun story, not a technical publication. When we say “cortical” curves we are referring to the acronym “CAEP” which stands for Cortical Auditory Evoked Potentials which we discuss later.

“Cortical” responses allow us to “see” if the patient is “detecting” a sound. Many patients, old and young, cannot respond to a hearing test by raising their hand or repeating a word. Infants cannot talk to you as you adjust the amplification. Their baby brains, however, produce cortical responses that give us much insight into their perception of speech sounds.

The use of “cortical” measurements will not replace ABR, OAEs, or any other standard test. “Cortical” tests give us a new way, a better way to see if amplified speech sounds are “audible” (detected). This concept will become clearer as we continue our story of Suzy and Danny.

## Now back to the kids.

Hours after Suzy and Danny were born, they both failed their newborn hearing screenings. They were referred to Dr. Judy Smith, a local audiologist. Dr. Judy obtained extensive histories. She did ABRs, otoacoustic emission tests (OAEs), tympanometry and other tests on these little babies. It was obvious they both had noteworthy hearing loss and needed amplification, so she made impressions for earmolds and scheduled them for a Pediatric Hearing Aid Evaluation.

## But now what?

If you are Dr. Judy and you determine Suzy has a substantial hearing loss and Danny has a more profound hearing loss, how do you determine the exact amount of gain each infant needs? Do you put all of your “faith” in the target recommendations of NAL or DSL software? Do you use the guidelines you learned in graduate school? The most important question is, “*How do you determine if the amplification levels you select for Suzy and Danny are correct?*” Dr. Judy needs a machine that can tell her whether or not Suzy and Danny are perceiving speech—their neural systems are detecting speech sounds—at appropriate levels after they are fitted with hearing aids.

## We have great news!!

With great excitement and pride, Frye Electronics in Oregon and The National Acoustic Laboratories (NAL) in Australia are pleased to introduce HEARLab, a test instrument used to measure cortical responses—with and without hearing aids. Currently, there are two parts to HEARLab: ACA (Aided Cortical Assessment) and CTE (Cortical Threshold Estimate).

ACA is used to evaluate hearing aid fittings using real speech sounds presented through a speaker. You view the evoked cortical responses of a tiny infant who is wearing hearing aids. In this story we call ACA the “aided” tests. It is more properly called NAL-ACA (National Acoustic Labs – Aided Cortical Assessment) a study of evoked cortical responses while hearing aids are worn.

CTE is used to estimate unaided hearing thresholds. Tones are presented via insert earphones or a bone vibrator. The evoked cortical responses are studied. In this paper we call CTE the “threshold estimates” or “threshold tests.” We will discuss both ACA and CTE.

### ACA: Aided Cortical Assessment

Dr. Judy has many diagnostic tools at her disposal that she uses to evaluate the hearing ability of infants. But, until now, none of these tests could directly confirm whether or not the amplification was stimulating the auditory cortex. Suzy and Danny are only a few weeks old and we cannot ask them, “Can you hear the sound of my voice?” In the past it was almost impossible to evaluate the appropriateness of the amplification.

With HEARLab, we now have a new tool that directly measures the infant’s cortical responses so we know if amplified speech sounds are detected by the infant wearing hearing aids.

After a little training, you learn to see whether or not the cortex is responding when speech sounds are presented. A hearing aid is fitted in the usual fashion. The speech consonants /m/, /g/, and /t/ are presented to the infant using *sound field speakers*. Insert earphones cannot be used; you need room for the hearing aids and ear molds to be placed over and in the ears. The cortical response is then measured and viewed on the monitor along with information about testing sufficiency and whether or not a cortical response is present.

## Speech-Like Test Sounds

NAL did numerous studies using many different types of sounds to evoke cortical responses. It was decided to limit the speech-like test sounds to three test stimuli: /m/, /g/, and /t/. These consonants were extracted from continuous discourse spoken by a female and filtered to match the International Long-term Average Speech Spectrum (ILTASS). A high-pass filter was also applied at 250 Hz to /t/ and /g/ to remove additional unwanted low frequency noise.

When you measure the level of these speech sounds (with a sound level meter set to an “impulse” time setting) they are within a few decibels of the long term level of speech from which they were extracted. For example, if the cortical testing is done with these consonants set to 65 dB, they will be presented very close to the level they would have in speech whose long-term level was 65 dB SPL.

The inter-stimulus duration is 1125 msec. The stimulus duration is 30 msec. A hundred epochs can be presented in about two minutes.

These brief consonant sounds have very little of the vowel transition. They are essentially vowel-free stimuli that have spectral emphasis in the low, mid, and high frequency regions. Figure 1 shows the one-third octave spectra for these three speech-like sounds. They have the potential to give diagnostic information about the perception of speech sounds in different frequency regions.

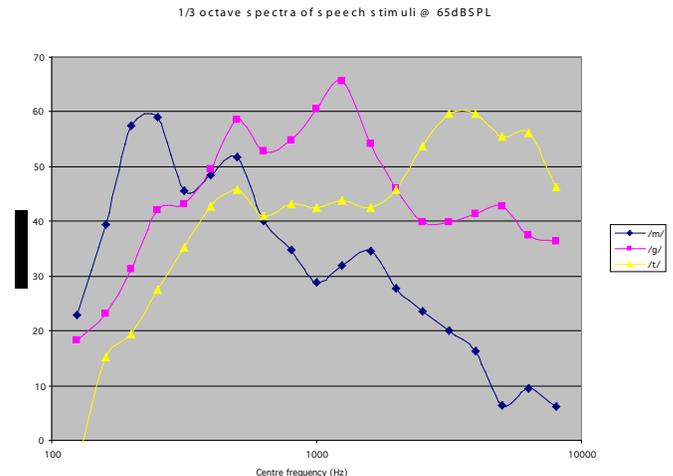


Figure 1: The one-third octave spectra for three speech sounds: /m/, /g/, and /t/.

## Cortical ≠ ABR

The “cortical” response (CAEP) is the electrical signal produced by the neurons in the auditory cortex of the brain. We are NOT talking about the brain stem response measured in an ABR test that happens in the first 10 milliseconds after a stimulus has been presented. Cortical measurements are done while the child is awake. Brain stem tests are often done with the child asleep. The “Cortical” response happens much later, roughly 50-500 milliseconds after the onset of the signal. We will return to this topic again later in this paper.

## The Objective for the Aided (ACA) Test

*We want to be sure the infant/child gets the information across the frequency spectrum of normal conversational speech. Low, mid, and high pitched speech-like sounds are presented to the infant at the normal speech level (65 dB SPL) while the infant is wearing a hearing aid. The cortical responses are studied.*

If needed, the amplification can be changed and the cortical curves re-evaluated to study the fitting.

If no response is observed with a high level of amplification, and if the averaged waveform has a sufficiently low level of residual noise (more on this later), supplements to hearing aids (cochlear implant, education using sign language etc.) can be considered.



Let’s take a look at how Suzy and Danny were fitted with hearing aids. Suzy was born with moderate-severe hearing loss. Danny has mixed profound hearing loss: complicated because he has fluid in his middle ears.

Two questions haunt the professional fitting hearing aids. First, “Is the patient getting enough sound to develop speech and language? And second, “Is the patient getting too much sound—am I causing discomfort or endangering the patient’s hearing with excessive amplification?” We will look at these two questions as we discuss the stories of Suzy and Danny. Cortical testing helps us directly answer the first question, and sometimes gives us insight into the second question.

## Suzy

Suzy is a beautiful, three month old, infant girl. She is very little! She has a quiet mother, an old-fashioned unsupportive father who is in denial of her hearing loss. As Suzy grows up, her family will say she is a graceful, shy, quiet, but a sophisticated young lady. The story of Suzy has a happy ending. With well-fitted hearing aids: She hears well. She gets a top notch education and a job she loves. She becomes very successful.

But, before this wonderful story can happen, Dr. Judy has to fine tune this tiny infant’s amplification and deal with a father who does not believe Suzy should be wearing hearing aids.

Suzy is held in her mom’s lap, electrodes are placed on the top of her head, her forehead and mastoid. She is restless but calms down after she nurses. Heavy nursing is avoided as infants tend to go to sleep if they nurse a lot.

Suzy wants to go to sleep but is kept awake by a video, some toys, and baby-friendly books while the tests are done. Testing cannot be done if the child is asleep. Sleep has various stages and most of them result in diminished or absent cortical responses (relative to those that occur while we are awake)— just as we are generally less sensitive to sound when we are asleep. Infants like to sleep and they go to sleep quickly. Without EEG equipment and training, it is difficult, perhaps impossible, to judge if they are lightly asleep or deeply asleep. It is strongly recommended that the child be awake for the tests.

Suzy is encouraged to watch a silent cartoon on TV. The video entertains her and helps to keep her quiet while the tests are done. At times, she becomes bored watching the TV, so her father entertains her with her beloved teddy bear. When that does not work dad uses a light-up toy and a mirror. Babies

love to look at themselves in the mirror.

Dr. Judy has many “distracters” she uses to keep the babies entertained. The child must be calm while the test is being done. These distracters include:

- Small bright colored soft toys and puppets.
- Light-up toys.
- A TV showing a silent colorful cartoon.
- Hand held mirrors.
- A shiny, sparkly ball on a string.
- Some kids’ books with colorful pictures—little babies love black, white, and red contrasting colors and pictures of other babies.
- Squeeze toys that changes shape when you squeeze them. Avoid the ones with squeakers inside.
- Blowing party soap bubbles—silent and fascinating to most babies.

Stores like Party City have a large supply of fun-to-look-at and fun-to-play-with toys.

“Whirly” light up toys that go round-and-round are great distracters during electrode placement. They can be a little too noisy during testing.

When the sparkly-ball-on-a-string is used, dad is told to not to move it around too much. You don’t want the child’s eyes and head moving around excessively. You want to keep “muscle noise” to a minimum.

Suzy is fitted with moderate gain hearing aids; the left hearing aid fitting is arbitrarily studied first. Speech sounds are presented at a normal speech level (65 dB SPL) from a nearby speaker. The CAEPs, Cortical Auditory Evoked Potentials, are viewed on the monitor.

The real-ear equipment Dr. Judy uses recommends 35 dB of ave. gain (the gain averaged for the frequencies of 500, 1000, and 2000 Hz) for medium intensity input signals. Note: for simplicity we use term “ave.” (averaged) gain.

Dr. Judy is worried about over amplification in Suzy’s case; she has a marked startle response when the hearing aids are switched on. Dr. Judy’s testing strategy is to do the tests at the recommended level, i.e. 65 dB SPL. Then, if Suzy is not too restless, she plans to reduce the gain and continue the study.

The cortical test is done with the stimulus set to 65 dB SPL, normal speech level. As the data start to accumulate, the cortical response is quickly and clearly seen on the monitor, and the statistical calculator indicates that it is a “real” response—i.e. one related to the stimulus. Dr. Judy is delighted that the fitting is in the right ball park. These gain settings are then recorded as Suzy’s recommended amplification level. The right hearing aid is then fitted and the process repeated.

After the initial ACA tests Dr. Judy markedly lowers the gain of one of the instruments and she restarts the study. After about 100 epochs she stops the test; the cortical response was obscure, not as clear as the initial tests. She concludes the initial results provided better amplification. She is now less concerned about the possibility of over amplification.

Note: In Suzy’s case, comprehensive diagnostics tests (OAEs, ABRs) were done before the cortical measurements (ACA) so no “unaided” testing was done. If OAE and ABR information had not been available, then the first cortical measurement would have been an “unaided” study using tonal stimuli.

If you suspect the child has auditory neuropathy/dys-synchrony it is recommended you do “unaided” tests (CTE) before the “aided” tests (ACA). It is difficult to predict the audiogram from the ABR for these babies.

## Danny

Danny is a robust, beautiful, high-energy infant. His mother had a difficult, long-duration labor that ended in an emergency cesarean section. Danny was large at birth, over nine-and-a-half pounds; a well developed infant. His Apgar and other birth scores were all normal.

Danny is held by his father and intently watches TV while the cortical tests are done. Danny is tested while wearing his high power hearing aids (one at a time). The test signal is set to 65 dB SPL. Dr. Judy sets the “ave.” gain of the hearing aids to 55 dB, a flat frequency response.

Danny has fluid in his middle-ears that has probably been there since birth. His tympanograms are flat. A note about middle-ear fluid was placed in his chart. He will be rescheduled sooner-than-nor-

mal for follow up visits to monitor the changes in his hearing due to this conductive component. Less gain will be needed as soon as the fluid clears out of his ears.

As Danny's testing with the hearing aid progressed, a waveform that looked a bit like a cortical response was observed, but the statistical calculator indicated that it was not significantly different from random noise. Dr. Judy stopped the test and increased the hearing aid gain by 10 dB. Danny was hungry so his mother fed him a little while Dr. Judy was adjusting the hearing aid. The test was restarted, and everyone cheered when clear cortical responses with correspondingly high significance levels were observed.

When hearing aids are fitted to adults, we spend a lot of time asking the patient, "How does it sound? Is my voice a little too loud or a little too soft?" HEARLab give us the ability to present speech signals to infants and observe cortical responses that are highly correlated with perceived speech. The tests are done with the hearing aid set to the audiologist's recommended level.

If the desired cortical responses are observed, the fitting is "verified"—however the word "verified" should not be taken literally. It is more accurate to say the fitting is "in the right ballpark" or "a level has been found where the input signal actively stimulates the auditory cortex". When cortical responses are observed, we should not assume the hearing aid fitting needs no further review. Hearing aid fittings on infants are "works in progress". Continuous monitoring and repetitive re-evaluations are needed.

If the desired cortical responses are not observed, and the residual noise is low enough that a response should be visible --- if one was actually there, --- then everything about the fitting must be checked:

- Are the electrodes still properly attached?
- Do they still have sufficiently low impedance?
- Is the child still awake?
- Were the thresholds on which the prescription was based, correct?
- Were the thresholds properly transferred to the prescription software?
- Is the response of the hearing aid (measured in a coupler) the one prescribed for this degree of hearing loss?

- Is there anything unusual, such as a blockage or a very loose fit, about the earmold?

Typically, the hearing aids are programmed by the audiologist prior to the child/infant coming to the office. The child and the supporting family then come to the office and the hearing aids are fitted. Soon after, the child is scheduled for "cortical" tests. On a rare, very calm peaceful child, the cortical tests can be done while the hearing aid is attached to a separate computer used to program the hearing aid. On the more typically active child the addition of extra wires and computer make everything too complicated. The gain/output controls can be adjusted to the desired level at which CAEP responses are seen on the HEARLab monitor.

The example of Danny who has middle ear fluid helps to reveal one of the major advantages of the HEARLab tests. The aided cortical assessment includes all parts of the "pathway of hearing." A test signal is emitted from a speaker and the response is observed in the auditory cortex. Many factors markedly impact the amount and quality of sound as it passes from the outside world, through the hearing aid and ear and into the brain. These include but are not limited to:

- The filter in the hook of the BTE.
- The space (residual volume) between the earmold and eardrum.
- The presence or absence of middle ear fluid.
- The integrity of the cochlear hair cells.
- The integrity of the ascending auditory nerves.

We tend to think of the "pathway of hearing" as the steps or stages in hearing from the outside world to the brain. We need to remember that the auditory cortex is part of the "pathway." Brains mature rapidly after birth. The auditory cortex of infants with normal hearing "organize" and "mature" rapidly in response to sound stimulation. HEARLab tests incorporate many variables. HEARLab tests take us directly to the cortical response that correlates well with the perception of speech.

In Danny's case, "poorer" hearing (an absent ABR) and the presence of middle ear fluid caused Dr. Judy to worry about "under" amplification.

In Suzy's case Dr. Judy was worried about "over" amplification. Suzy's initial "aided" (ACA) cortical tests looked good. Dr. Judy extended the tests using a much lower gain setting: Poor quality cortical

responses were seen. Dr. Judy interprets this data to mean the auditory neural cortex system was not adequately stimulated at the lower gain setting. It seems the amplified sound was below Suzy's auditory threshold levels, i.e., Suzy's neural system was not "detecting" the speech-sound used for the test. So she rejected the possibility of using significantly less gain.

When Dr. Judy started Danny's test, poor quality cortical responses were seen. Dr. Judy interpreted this data to mean the initial fitting was "too weak," so she increased the gain of the hearing aids. Her judgment was confirmed when she saw good cortical curves at the higher gain/output settings.

All of us understand that high power hearing aids can be very harmful if fitted improperly. HEARLab is an exciting new tool that helps you evaluate a hearing aid fitting taking into account the extra efficiency of a tiny baby's ear: it is more efficient in the higher frequencies due to the smaller volume in the ear canal. HEARLab also help us see whether or not the presence of middle-ear fluid has attenuated the amplified sound to a level below threshold. Gain/output can be *indirectly managed* using cortical tests. However, please read the following note carefully:

### **Important Note!**

*If the gain/output of the hearing aid is much too high, you see "typical" cortical responses. Nothing in the data tells you that you are over amplifying this person.*

If the initial settings produce "good" quality cortical responses, the patient's auditory neural system is responding to the amplification. The test results do not tell you whether or not you are "over" amplifying the patient. Mindful of this fact, Dr. Judy Smith was cautious with the gain level for Suzy.

If, you adjust the hearing aid to the prescribed gain level and you run a cortical (ACA) test with the hearing aid on: If, the test conditions are good (quiet, the baby is awake) and the cortical response is "*poor or absent:*" You may need to review the hearing aid prescription, the estimate of the hearing loss may be too low (poor quality ABR results, etc). When the initial test did not produce a "good" cortical curve, Dr. Judy was prepared to increase the gain level for Danny because all of his "hearing test" data pointed to a profound *mixed* hearing loss.

Let's turn our attention to the family of the patient.

### **Dealing with the Family**

Suzy's father was especially problematic. He is an example on how the HEARLab test results can help in counseling situations. Suzy's father refuses to accept the fact that Suzy has a hearing loss and needs to wear hearing aids.

When Dr. Judy realized the family was having problems, she scheduled them for a counseling session. She used the cortical responses to show the father that Suzy had a hearing problem. The conversation went something like this:

"Suzy's brain can show us whether or not she is hearing." Pointing to the cortical responses saved in Suzy's file Dr. Judy said, "Look, here is the response Suzy's brain makes when she wears the hearing aids. The neurons in her brain are telling us, '*I can hear! I can hear!*' When we remove the hearing aids, these responses disappear! She cannot hear! When she wears the hearing aids she will hear well. If we remove the hearing aids, she will not hear, and she will not learn to talk. Her ability to learn depends on her ability to hear. You need to help make sure she wears the hearing aids and they are working well."

The visual response produced by HEARLab helps parents see the result of the amplification. It is very comforting to "see" that the amplification is working well. If families are having trouble accepting that their child needs to wear amplification, it can be very helpful to show them a graph that shows no brain responses to speech sounds without hearing aids, and good brain responses with hearing aids.

### **Let's return to our story about Danny.**

HEARLab measurements can be done easily on a child that cooperates by being quiet. Danny is a precious little baby who seems to like the TV when he is in the office. Luckily today the TV has an almost hypnotic effect on him. Tympanograms are obtained quickly. The amplification is lowered as soon as the middle-ear fluid is gone from Danny's tiny ears and the aided cortical tests are repeated to make sure he is still able to detect speech sounds with the lower gain settings.

Some children like Danny will need additional gain from the hearing aids when they go through periods of middle ear fluid. HEARLab simplifies the decision making process. Cortical tests confirm the adequacy of the levels provided by a hearing aid fitting. HEARLab gives the audiologist a tool that can be used to study the needed gain.

We know through years of seeing children with middle-ear fluid that the amount of a conductive hearing loss can vary anywhere from a small (5-10 dB) loss to a large (35-45 dB) loss. Pneumo-otoscopy and tympanometric studies are used to diagnose middle ear fluid. However, it is impossible to accurately estimate the size of the conductive component created by middle ear effusion without air and bone conduction measurements.

We have seen older children with middle-ear fluid that have a 35 dB conductive hearing loss in the low frequencies on “Monday” and have normal hearing in two weeks when the fluid dissipates. Hearing levels can change quickly when middle-ear fluid is eliminated. The tests done with HEARLab help to remove this complication. The effect of middle-ear function is factored into the tests.

In Danny’s case, Dr. Judy’s initial gain recommendation was increased as a result of the initial cortical test. Dr. Judy’s fear of over amplifying Danny was lessened because she understood that part of his loss was conductive. When the middle-ear fluid resolves and Danny has normal tympanograms, his hearing aid gain is reduced and his cortical responses re-evaluated.

### **Who is behind this system?**

NAL, The National Acoustic Laboratories, in Sydney Australia is a large sophisticated research facility. Audiologists and engineers at NAL set out with the explicit aim of coming up with some method for evaluating hearing aid fittings on babies diagnosed through universal newborn screening. Cortical responses quickly emerged as the most practical method.

If you have not followed the development of “cortical” tests you might believe these tests are only a few years old. In fact, cortical responses have been measured by researchers internationally since the 1960s. Their use for measuring hearing thresholds was overtaken by ABR in the 1980s. ABRs had the advantage that the response shape was more

predictable, and responses could be observed on sleeping babies. Unfortunately, the very brief stimuli used for ABRs, and the requirement that the baby be asleep, make them less suitable than cortical responses for evaluating aided performance. Cortical responses also more completely measure the auditory system.

NAL has built on the significant research done internationally on cortical responses, and has in particular focused on how to make the test as automated as possible, with as much interpretation as possible done automatically by the equipment. NAL has published some of their research on this topic, with more in the publication process.

Research, particularly that by North American researchers Curtis Ponton and Anu Sharma, has shown that cortical responses can tell us more than just whether or not the sound is perceived. The latency of the positive peak in infants and young children is highly correlated with the amount of exposure to sound that the child has had. For babies with normal hearing, the latency decreases from over 200 ms at birth to around 120 ms by age 2 years.

Infants who do not receive adequate stimulation until receiving a hearing aid or cochlear implant at, say 12 months of age, initially have latency similar to that of a newborn baby. Over the following year of exposure to sound, the latency will decrease by the same amount that normally occurs during the first 12 months of life. The latency of the observed response thus tells us about the maturity of the processing system within the cortex—maturity that can develop only in the presence of auditory stimulation. HEARLab includes a graphical representation of normal latency (given the age of the child) so that the maturity of the response of the individual child being measured can be assessed.

NAL has had a prototype unit in operation for a few years. The current production unit, HEARLab H 1000, incorporates many enhancements made over this time.

NAL licensed the HEARLab unit to Frye Electronics in Oregon who manufactures the system.

### **Where is “cortical” testing done?**

This paper discusses two modules: the “aided” (ACA) test and the “threshold prediction” test

(CTE). When you measure cortical responses with hearing aids, the usual input level is 65 dB SPL, not very soft levels. No special consideration for ambient noise needs to be made for the “aided” (ACA) tests. These tests can be done in a wide variety of reasonably quiet listening situations. Family members just need to be as quiet as possible when sounds are being presented. Of course we cannot stop infants from ‘talking’ during the testing but we can try to engage them in activities that keep noise to a minimum. Drinking from a baby training cup or eating soft foods (that don’t involve lots of chewing) can be a good way to keep a little one quiet and busy.

The primary consideration is the comfort of the patient. The infant must be relaxed and reasonably still. Most “room noise” like people talking at soft levels will be factored out by the averaging of the responses that occurs within the testing system. It is helpful but not necessary to do “aided” (ACA) tests in a “sound booth.”

Neuromuscular noise produced when the child moves or cries creates a disturbance in the responses, and when this disturbance is large enough to be recognized by HEARLab as an unusual occurrence; each epoch containing these high noise levels is omitted from the average. Either way, neuromuscular noise lengthens the measurement process: In the first case, a greater number of epochs must be averaged to reduce the noise down to low levels, in the second case; a greater number of stimuli must be presented so that the required number of epochs provide data that are accepted for processing. Consequently, it is important that the child be comfortable and quiet when the tests are done.

When “threshold prediction” tests (CTE) are done, the ambient floor noise in the room and the natural muscular noise of the child all become critical factors. As you attempt to test at lower and lower levels, all noise (acoustic and neuromuscular) becomes critically important.

Some infants, like children with cerebral palsy, are difficult or impossible to test because the “noise” generated by muscular contractions cannot be factored out from the test data. Some medications prescribed to special needs babies (e.g. anti-epileptic medicines) may also interfere with the response.

Here are some practical suggestions on testing.

Note: Lyndal Carter contributed many pages of practical suggestions to this document. They are included in the appendix. This following list was abstracted from Suzanne Purdy et. al.(Chapter Eight).

- The timing is very important. The infant needs to be settled and awake.
- If the infant is too active, the recordings will take too long and contain too much muscle activity.
- Pause the tests when the infant gets too vocal.
- Have everyone monitor the infant’s “state.” Infants fall asleep unexpectedly or can be close to sleep with their eyes open.
- Electrode applications need to be fast, painless, and secure since the infant will be sitting up, awake on the caregiver’s lap.
- Tell the family not to use cream or hair conditioner on the infant’s head prior to coming to the appointment as the electrodes can slide off.
- Drape electrodes away from the face and hands so that they are less likely to be noticed and pulled at by the infant.
- Use a lanolin-based cream or an adhesive remover wipe to assist in electrode removal as it is much more pleasant for the family if you don’t upset baby by just pulling off the electrode sensor pads when the test is finished.
- Make sure the hearing aids have new batteries for the test. You don’t want a battery going dead during the test.

### **When is cortical testing done?**

The overall process can be summarized as: (1) screening, (2) diagnosis, (3) fitting, (4) cortical evaluation, (5) then long term follow-up and fine tuning.

1. Many infants receive a mandatory hearing screening at birth. Children who fail the screening are referred to an audiologist who specializes in pediatric evaluations.
2. ABR or ASSR, otoacoustic emission (OAEs), and immittance audiometry (tympanometry and acoustic reflex testing): are often used in these evaluations. After the initial pediatric hearing evaluation, children who

have hearing problems are scheduled for a pediatric hearing aid evaluation: impressions are made, and hearing aids are ordered.

3. The aids are programmed when they are received from the factory: The audiologist uses current guidelines (NAL or DSL i/o) to prescribe the gain and output. The child and the family are scheduled and the hearing aids are fitted. Considerable counseling is done and the family is taught how to care for the hearing aids.
4. The child is then scheduled for cortical testing. It is at this point that the HEARLab becomes invaluable. The HEARLab testing sequence is ideal for infants who have documented hearing loss and have been fitted with hearing aids. HEARLab helps to confirm that the hearing aids have been adjusted to the prescription and that these settings are indeed meeting the child's needs. Cortical tests are also ideal for any child that has developmental delay and cannot respond reliably to behavioral testing, or for that matter, people of any age who cannot reliably respond.
5. Follow up visits should be done regularly to ensure that the child is receiving proper amplification. Depending on the clinic, visits should be done every 2-4 weeks,

According to Harvey Dillon, "...cortical tests are being positioned as a very informative evaluation tool, rather than a fitting tool. It is anticipated that further research and evaluation might show these measurements to be so useful that this approach will become a fitting tool rather than an evaluation tool. For now clinicians should make their own decisions on adjusting amplification, and what to do if HEARLab says there is no response, even though residual EEG noise has been reduced to a level where a response ought to be visible, if one is indeed present."

### **Early intervention is critical.**

Early detection and treatment of hearing is critical. Here is a quote from the NAL annual report. "Newborn hearing screening programs aim to diagnose hearing-impaired infants within the first few weeks of life so that early intervention, including the fit-

ting of hearing aids, can be provided before the age of six months. This is important because it has been demonstrated that children diagnosed *before* the age of 6 months develop significantly better speech and language than those diagnosed after this period. Clearly, appropriate amplification is a crucial factor..." Yoshinaga-Itano et al. (1998).

### **What about adults?**

The tests discussed above (ACA) can be used to evaluate hearing aid fittings on people of any age, not just infants and babies. Later we discuss how the cortical response changes as infants mature.

HEARLab also comes with CTE (Cortical Threshold Estimate) which is used to estimate hearing thresholds. Tonal test signals can be presented using insert earphones, or a bone vibrator. Insert earphones reduce the ambient noise and allows us to do "hearing tests" at lower intensity levels without hearing test chambers. They are also more accepted by small children than are supra-aural headphones, and provide greater inter-aural attenuation, thus reducing the need for masking.

Clinical audiologists see a wide variety of difficult-to-test patients. Some patients have physical or emotional disabilities that prohibit them from cooperating fully with a typical hearing test. Other patients are highly motivated to have "hearing loss" for medical or legal reasons. Cortical tests are ideal for difficult-to-test patients of any age where objective "biologically based" responses are needed. These tests are especially helpful for patients with exaggerated hearing loss or a patient involved in a medical/legal disputes where "objective" data are needed for legal reasons. For people with sensorineural hearing loss, cortical responses are usually visible within 10 dB of behavioral thresholds.

### **A Little Information about Brains.**

If you have recent training in ABR you might want to skip this section.

Nerve cells (neurons) produce electrical signals throughout the body. There are huge numbers of neurons in the brain. When activated, the neurons in the brain make a lot of electricity. When a large group of neurons fire in synchrony, they produce enough electricity that we can detect and record these responses using "surface" electrodes on the scalp.

According to Teplan: The human brain starts maturing long before the baby is born and electrical activity is seen around 17-23 weeks of prenatal development. At birth the number of neurons is huge (10 to the 11th power). Adults have about 500 trillion synapses... "...the brain can be divided into three sections: cerebrum, cerebellum, and brain stem. The cerebrum consists of the left and right hemisphere with a highly convoluted surface layer called cerebral cortex. The cortex is a dominant part of the central nervous system. The cerebrum contains centers for movement initiation, *conscious awareness of sensation* (our italics), complex analysis, and expression of emotions and behavior. The cerebellum coordinates voluntary movement of muscles and balance maintaining. The brain stem controls respiration, heart regulation, biorhythms, neuro-hormone and hormone secretion. *"The highest influence to EEG comes from the electric activity of the cerebral cortex due to its surface position."* (Our italics) (From M. Teplan, Fundamentals of EEG Measurement, Measurement Science Review, Vol 2, Section 2, 2002).

"Evoked potentials, also called event-related potentials, are made by external stimuli (our test signals). Evoked potentials are extracted from sets of recording by the digital averaging of epochs. An epoch is a recoding period, time-locked to the repeated presentation of the test signal. The spontaneous background EEG fluctuations, which are random relatively to the point in time when the stimuli occurred, are averaged out, leaving the event-related (evoked) brain potential. These evoked electrical signals reflect only that activity which is consistently associated with the stimulus processing in a time-locked way. *"The evoked potential thus reflects, with high temporal resolution, the patterns of neuronal activity evoked by a stimulus."* (Our italics) (from Teplan, same reference as preceding paragraph).

It is important to realize that while the averaging process reduces the level of noise arising from all sources other than neural circuits responding to the stimuli, it never totally eliminates this noise. HEARLab uses the variation between the individual epochs, combined with the number of epochs included in the average, to estimate the residual noise in the averaged response. It displays this as a number in microVolts, and also uses this value to control a set of traffic lights. The lights go green when the residual noise is less than 3.4 microVolts.

NAL's research has shown that if the residual noise is less than 3.4 microVolts, cortical responses from young children can almost always be seen when the stimulus is 10 dB above behavioral threshold.

## What Is a HEARLab system?

### The patient's point of view

There are two very different perspectives of HEARLab: the family and patient point of view, and the Audiologist's.

The HEARLab unit allows audiologists to create a picture of the electrical activity of the brain when speech sounds are detected in the auditory cortex. We see the evoked responses on the computer monitor and the test results are saved in the computer's data base. This is important information to professionals, but *exciting emotionally-loaded information to the parents of these children*. Suzy and Danny's parents are delighted with the "graphs" that show their babies can "hear" speech with their hearing aids on.

We should *give colored copies of these evoked responses to the patient's family*. Parents treasure items like the "ultra sound" recording of the "baby" three months after conception. We need "patient friendly" words to put on our graphs, something like, *"The first sounds Suzy heard!" Or, "Danny's brain saying, Yes, I can hear!"*

Most "labs" have photo boards that are full of "thank you" letters and photographs of the patient. We suggest you make space for this board and ask patients for thank you letters and photos to display on the board. This board will become the "heart" of HEARLab. Parents will be drawn to this "success" board and the many photographs of beautiful infants.

There are three "parts" to HEARLab: the computer, the stimulus controller box, and the Electrode Processor box.

### The computer

Thirty years ago an ABR unit was expensive and had limited processing power. Today's computers are a thousand times better. Today's computers have more memory and a higher processing speed than main frame computers thirty years ago. HEARLab presents sounds and records the tiny electrical signals produced in the brain, while re-

ducing, by averaging, the background noise made by the brain. Years ago, you needed to spend a lot of money on a computer to do this. Today it can be done with a normal computer. A “gig” of RAM combined with the modern processing speed and huge storage abilities of computers gives us all the signal processing capabilities we need.

The HEARLab computer is a typical off-the-shelf computer. It comes with the software installed. One word of warning! Do not be tempted to install any other software on this computer. HEARLab is a “dedicated” computer designed for a single purpose. The integrity of the system has to be protected so the processing capabilities can be maintained. The software is designed to “reject” the installation of additional programs. If you “bypass” these built-in protections, the system will crash and Frye will not furnish software support! So please, make sure that all people who use the HEARLab system understand it is a “dedicated” system and must only run the HEARLab software.

The HEARLab software has a database used to save all the patient information and the test results. It also has “work” screens used during the testing and reporting procedures. For more information see the HEARLab NAL-ACA reference guide.

### **The Stimulus Controller (SC)**

The computer sends commands to the Stimulus Controller through the USB port connection. Signal generation is also done here. The system does not use a sound card found in many PCs. This SC unit contains signal generation circuits, microphone amplifiers and stimulus amplifiers.

SC has a number of connectors on its back panel that are used to drive the sound field speaker(s), the insert earphones and the bone oscillator. Other connectors that have other uses are seen on the back panel. This unit has its own power supply and must be plugged into a wall outlet. It supplies power to the electrode processor box via a standard multi-wire cable.

### **The Electrode Processor box**

This box receives direct signals from the patient and it contains a meticulously crafted system of isolators that separates the main power circuitry from the patient. The separation prevents the possibility of accidental electrical shock. The primary

amplifier is found in the SC unit which is electrically isolated from the patient.

The electrode processor box has amplifiers and connectors for electrodes. There are three electrodes that will be used initially in the first software module: one active (non-inverting) electrode, one reference (inverting) electrode, and one ground electrode. However there are five spaces for future use that can hold: three active electrodes, one reference electrode and one ground electrode.

This box sends a tiny electrical signal to the electrodes and measures the resistance between the active and ground electrodes and also between the reference and the ground electrodes. The cortical signals are picked up by the difference between the signals present at the three electrodes. The active electrode is placed at the top of the head, the reference electrode at the mastoid, and the ground electrode at the forehead.

This system uses the new “active” type of electrodes that produces much stronger signals right at the head. The active and reference electrodes have the active circuit element on a miniature circuit board which is encased in a rubber molded housing. The main result of this is that the leads between the head and the rest of the electronics are much less prone to external interference than is the case with normal passive electrodes.

The electrode is connected to a snap connector that takes standard blue EKG sensor pads, preferably kid size. Electrodes are color coded: Black is ground (forehead). Blue is reference (mastoid). Yellow is active (vertex). Colors are marked on the panel and on the electrodes themselves.

Before the start of each test, tiny electrical signals are automatically delivered to the head by the electrodes to measure the skin impedance interface. A color bar is shown for the reference and test electrode: green indicates good impedance (0-5k ohms), yellow is satisfactory (5-10k ohms), marginal (10-15k ohms), and red (greater than 20 k ohms) indicates poor impedance. It usually helps to reduce the impedance seen by the electrodes; the green range is better than the other colors. Be sure the skin is *cleaned well* before applying the electrodes.

### **Clinical Judgment & Expertise**

Older brain stem units had dozens of controls; most of them critically important to each measurement. In contrast the new HEARLab unit looks very simple to use. All of the decisions that are made for filtering, stimulus timing, and data viewing are built into the software. Much of the complexity has been removed.

The software provides easy-to-read information about the reliability of the response, and whether there has been sufficient averaging to reach a conclusion that no response is present. This critical information is presented with a green traffic light that illuminates when adequate samples have been obtained. Prior to this point in the test it is wrong to conclude that the child is not "hearing" the sound. The lack of a cortical response is meaningless until adequate samples have been made. The response may just be buried in the noise, i.e. more sample may be needed to average the noise to a lower level.

Do not get the idea, however, that the need for clinical judgment and professional expertise has disappeared. It has not. The value of the data will completely depend on the skill and experience of the clinician. The clinician also has a vital role in ensuring that testing conditions are optimized and explaining the testing and results to families.

Cortical testing can currently be done without HEARLab, however, the complexity of the system requires the clinician to be an expert electrophysiologist and the cost of the system is substantial.

There are many variables that can alter the results of a test; a few of these include: restlessness, sedation, age of the patient, sleepiness, attending or not attending to the task, sweating from crying or hyper activity, electrical interference, developmental delay, and nervous parents.

All patients present different challenges. The protocol must be tailor-made for each patient. The clinician must always be on their toes and be prepared for anything that comes their way. The machine appears to be very simple to use:

- It has few buttons to work with.
- It automatically indicates when a response is present.
- It automatically indicates when residual noise is low enough to take seriously the absence of a response.

In spite of these technological improvements, the responsibility for the audiologist is still considerable. The clinician must be experienced and be able to read results and understand them and ensure they tie in with other audiological findings. They should also expect to get different results for each patient and be prepared to handle them accordingly.

### **Suzy's Follow-Up Visit**

After Suzy had worn her hearing aids for about a couple of months she was evaluated again with HEARLab as part of her periodic review. Suzy had acclimated to wearing the hearing aids and the initial responses were good. Now, Dr. Judy was concerned about the gain in the lower frequencies. Dr. Judy had initially set the "ave." gain to 35 dB and the frequency response (the slope) to a 6 dB roll off. This was done because Suzy's diagnostic hearing tests had indicated a moderate loss not a profound impairment. There is a history of genetic hearing loss in Suzy's family, so Dr. Judy had wondered if Suzy had a "cookie bite" audiogram or a more traditional "flat" loss. The slope of the frequency response was initially selected to be rather cautious. Dr. Judy did not want to over amplify the lower frequencies in case Suzy happened to have good hearing in that zone.

During the follow-up test Dr. Judy noted that the low frequency cortical response to the /m/ stimuli was unclear. She increased the gain in the lower frequencies by 10 dB and the tests were repeated. This adjustment produced a marked improvement in the cortical response for the low frequency emphasis speech stimulus /m/. Judy was delighted.

### **Danny's Follow-Up Visits**

Precious Danny was seen several times in an attempt to deal with three problems:

- middle ear fluid,
- feedback, and
- poorly defined cortical response for the high-frequency emphasis speech sound /t/.

A month after Danny was fitted with hearing aids the middle ear fluid disappeared; then returned later. Dr. Judy attempted to give Danny enough gain so cortical responses could be visualized however increases in gain precipitated feedback. Sev-

eral sets of earmolds were tried. Finally, a different set of hearing aids with improved feedback cancellation capability were used and the feedback problem was temporarily solved.

Whenever the middle-ear fluid returned, Dr. Judy increased the gain in the low and mid frequencies, not the high frequencies, as increases in high frequency gain often produced feedback (the effects of middle-ear fluid are usually observed in the lower frequencies, not higher).

While Danny's case is challenging and frustrating, HEARLab gives you a powerful tool that helps you decide how aggressively to amplify various frequency zones. Without cortical measurements, a clinician may be tempted to make a large permanent reduction in high frequency gain to avoid feedback. The HEARLab test helps to show us the effects of changes we make to the hearing aid response. We can check to insure we have not compromised the response to the extent that we no longer see cortical responses for all three speech sounds.

In Danny's case the response for the high-frequency speech sound /t/ is often weak: the inbuilt statistical test indicates that a response is not reliably present. This may be because the high-frequency gain in the hearing aid is turned down to avoid feedback. However, as an experiment, Dr. Judy Smith covered Danny's earmold with a small amount of glycerin and she carefully inserted it: snugly. The glycerin formed an acoustic seal and eliminated feedback during the duration of the cortical tests. Under this condition, the gain in the instrument could be set to the "ideal" level, and cortical curves could then be clearly seen for all of the three speech sounds. This helps Dr. Judy decide that the change to the hearing aid response will be OK as long as well fitting molds are maintained for Danny.

Because Danny's middle-ear fluid problem kept returning, once the feedback problem had been resolved, Dr. Judy enabled the second memory in his hearing aids so that he had one gain setting that resulted in good cortical responses when his ears were clear and another gain setting that gave cortical responses when he had flat tympanograms.

Tests like this help us clearly see our goal: *adequate amplification in all frequency zones that produces the desired cortical responses*. It is difficult to achieve this

level of amplification on a day-to-day basis. But at least we have a clear view of our goal. Until proven different by additional tests when Danny is old enough for reliable behavioral testing, adequate amplification in all zones is important.

### **The three input levels: 55, 65, 75 dB SPL**

The HEARLab ACA unit has three input level settings: 55, 65, and 75 dB SPL. Most "aided" (ACA) testing will be done at 65 dB SPL to simulate the presentation of speech at the normal level. Most hearing aid fittings will be in the right "ballpark" and the aided tests (ACA) will confirm the adequacy of the fitting.

If "good" responses are observed at 65 dB SPL, it helps to reduce the input level to 55 dB SPL and gather additional data. If good responses are seen at 55 dB SPL you have no fear that the fitting has inadequate amplification: you may or may not have excessive amplification. On the other hand if there are no responses marked as significant at 65 dB SPL increase the input level to 75 dB and continue the tests. If "good" responses are seen at 75 dB you may decide that the hearing aid fitting is possibly "a little weak," i.e., you need to increase the gain a bit. If no responses are seen using the 75 dB SPL input, despite the 'noise' traffic light being green, you know that something is significantly wrong. You need to check the hearing aid and be sure the gain/output is at your recommended level. If so, you probably need to increase the gain/output and repeat the tests.

It is much easier to adjust the test level on the HEARLab system than to adjust the volume or gain of the hearing aid. Most volume controls are deactivated for these fittings. If you want to "drop" the speech intensity level 10 dB and re-evaluate or "increase" the intensity level 10 dB and re-evaluate, this can be done easily with the software.

### **Testing Restless Children**

Under ideal situations the patient is awake, calm and quiet. You use all test signals to evoke cortical responses at several intensity levels. However, some children and adults with special needs are difficult to test. For example, they may be hyperactive or be prone to involuntary movements, making it difficult to get them to sit still and allow you to properly place the electrodes and do the tests. In these instances you may want to consider chang-

ing your techniques or consider alternate testing procedures.

The speech-like signals, /m/, /g/, and /t/, used by the HEARLab ACA test have a much longer duration than the “click” used for ABR tests. It takes about a second for the brain’s response to each sound to die down and for the brain to be strongly responsive to the next sound. Consequently the sounds are presented a little over one second apart. This period from one sound to the next is called an epoch. Roughly 100 error-free epochs are needed before you see a “good” response—one that has a high probability of detection. The test time for 100 epochs is about two minutes. If the patient is excessively active, this time will increase, either because epochs are rejected, or because accepted epochs contain more noise than when the child is in a quiet relaxed state.

If the patient you are testing will not stay still for the entire test, try to get as much data as you can initially; then you can try again to get the remainder of the data later. For example, if you are checking a hearing aid fitting on a difficult-to-test patient you might use one speech sound—and the corresponding cortical response—for your “primary” testing goal. You gather data for this “primary” target quickly: you can gather the rest of the data at a later time. Later does not mean one month later, it is possible to let the child nurse or take a short nap and continue testing when they wake or after they are fed.

If you get one highly reliable “bit” of excellent data, you can often use this to insure you have a hearing aid fitting that is providing some benefit.

The sound field speaker is usually located near the patient (1 meter away) directly in front of the infant (at 0 degrees). A person who is distracting the child can sit on a little chair positioned so that the sound path from the speaker to the child’s hearing aid microphone is not obstructed. The opposite ear is occluded with the child’s own earmold and hearing aid switched off.

Some infants have tiny ear canals that become occluded easily. External ear tissue in infants is very soft and pliable and can collapse easily. Before cortical tests are given, it is a good idea to do an otoscopic exam and check the ear canals for debris and the middle-ears for fluid. Obviously, we do not want the ear canal to be obstructed during the test.

Earmolds and insert earphones hold the infant’s ear canal open. If you attempt to measure an “unaided” response on an infant with the ACA test using a sound field speaker; you need to be careful and insure the ear canal stays open when the child is held by the parent. If ear canal collapse is in question, switch to the CTE test and use insert earphones.

Also, little heads need to be supported. Have the parent hold the infant in their arms with the babies’ head held safely in their hand. Make sure that the hearing aid microphone ports are not obstructed when baby nestles back on Mom or Dad’s lap.



## Cortical Responses

### CAEP: cortical auditory evoked potentials

James W. Hall III, (New Handbook of Auditory Evoked Responses) discusses the Auditory Late Response (ALR):

- “The maximum response is typically obtained for moderate- (50-60 dB) verses high intensity stimuli.
- The response is highly susceptible to alterations in state of arousal (sleep stages) and to the effects of drugs, such as sedatives.
- Considerable intra- and inter- subject variability is common.
- There has been a recent resurgence of interest in clinical application of the response with computed evoked potential topography techniques and sophisticated stimulation (e.g. speech stimuli).”

Large evoked cortical responses are seen in infants at about 200 milliseconds. All speech sounds generate broadly similar CAEP responses. Close

inspection, however, indicates that the peak amplitudes and/or latencies vary systematically for some speech sounds relative to others. HEARLab indicates the probability that the response to each of the sounds /m/, /g/ and /t/ is different from each other. If any two of these responses are indicated as different from each other for an individual patient, then you can take this as an extra reassurance that complex processes are underway in the child's brain in response to the speech sounds. *However, there is no need for concern if the responses, though present, are not marked as different from each other.* Normal-hearing children can differentiate all the sounds of speech, even though the cortical responses are often indistinguishable from each other.

Figure 2 and 3 (from Suzanne Purdy) show the average curves for adults and infants. Notice the differences between the adult and infant curves. It takes considerable time for an infant's brain to mature. The early peak and trough seen in adult data become more apparent after the child is five to ten years old.

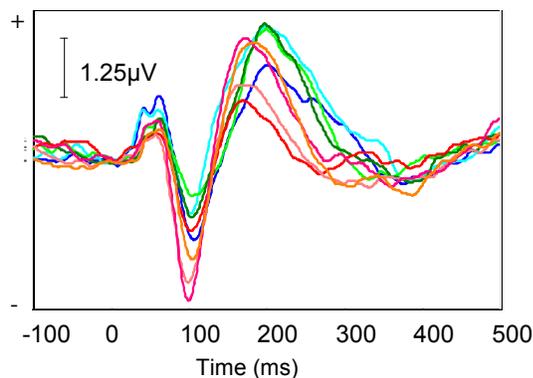


Figure 2: Grand average adult (N=14) CAEP waveform for the eight tonal and speech stimuli, recorded at Cz.

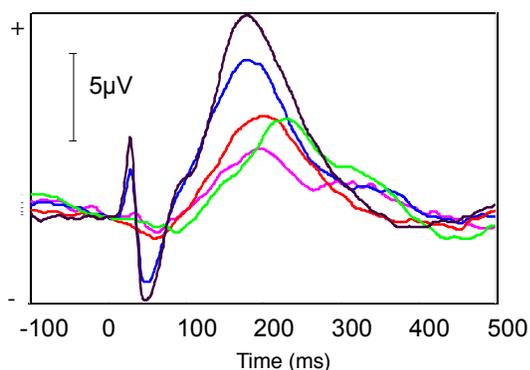


Figure 3: Grand average (N=20) infant cortical waveforms recorded at Cz.

The "curves" for adults (Figure 2) usually have an initial positive peak at about 50 msec. followed by an obvious trough (negative peak) near 100 msec. This peak and trough are poorly developed or completely absent in infants. By adult years (over the age of twenty) the dominant component is a negativity (80 – 120 msec) that is preceded and followed by positive components (i.e., P1 at 50 to 70 msec, and P2 at 150 – 200 msec) (Davis, 1965).

Notice that the vertical scale is  $1.25 \mu\text{V}$  in the adult graphic in contrast to  $5 \mu\text{V}$  for the infants. The response of the infant is more robust.

Infants often have a broad, rounded peak at about 200 msec. This is the "curve" HEARLab seeks to detect. When infants with normal hearing are tested, these curves are often seen. The intensity level of the infant response is much higher than that of the adult. To summarize:

#### Adult CAEPs:

- Have a positive peak near 50 milliseconds.
- And an obvious trough (negative peak) near 100 milliseconds.
- And a large positive peak near 200 milliseconds.
- The end of the curve—the tail—seen between 400-500 msec. is near zero or it curves upward slightly.
- The intensity of these responses is "subdued", i.e., much smaller than those seen with infants.

#### Infant CAEPs:

- Have a positive peak near 200 milliseconds
- The early peak and trough seen in adults are usually missing.
- The end of the curve (the tail) seen between 400-500 ms is decidedly negative, curving lower on the graph. This "negativity" is easier to see if you overlay adult and infant curves.
- The size of the response is robust, a lot higher than an adult.

In normal hearing infants, the overall shape (morphology: amplitude and time at peak) of the curves can change a little when different test signals are used. These differences tell us that the cortex of little babies is mature enough to tell the differences between various speech sounds. This is very exciting because all speech and language development

depends on the differentiation abilities of the brain. We want to adjust amplification to maximize these differences.

According to Suzanne Purdy, “CAEPs in infants evoked by some different speech phonemes differ in latency and morphology. This indicated different underlying neural representations of speech sounds and suggests that the information needed to differentiate the stimuli is available to the listener.” However, this is really only reliable at the group level. For the individual infant, therefore, a lack of difference between the waveforms for two different speech sounds is no cause for alarm.

Different stimuli create different responses. You can see this in Figure 7 by comparing the highest curve on the chart—the black line that represents /t/—with the one peaking farthest to the right—the green line that represents /m/. Low, mid, and high pitched speech-like sounds are included in the test to give us some indication regarding the infant’s hearing in different frequency zones.

### The “p” Value

A statistical analysis of each response is automatically calculated and displayed on the screen as the “p” value for each sound. This is a sophisticated statistical test (based on the Hotellings-t2 statistic) that helps the clinician determine the likelihood (probability) that the waveform observed was caused by the patient detecting the test signal. This statistic runs and updates itself in real time. Research on this “indicator” has shown it to be very reliable; often better than the clinician running the test. Do not rely solely on this analysis. The graphical display also shows the time region in which the peak should fall if the child’s auditory system has been exposed to sound for all of his/her life. If the child spent significant time without adequate auditory stimulation (e.g. prior to receiving an effective hearing aid fitting or a cochlear implant), then peak latencies longer than those in the shaded region may be observed. This is “normal” for a child who has been deprived of sound, and the latencies should decrease in the months following effective aiding or implantation.

HEARLab also displays p values describing the likelihood that the responses to different sounds are different from each other. These are based on another statistic – MANOVA, or multi-variate analysis of variance.

### Cortical vs. Brain Stem Tests

There is considerable published research on the attempt to use ABR in fitting hearing aids. Most publications point to the complications. Few authors report success. The primary test signal for ABR is the “click,” a sound that is very short in duration. Clicks tend to saturate the amplifier and they are incompatible with the processing delay of the digital hearing aid. A click cannot engage the compression circuits in a hearing aid in a realistic manner.

The cortical response is seen around 200 milliseconds in infants, and the stimulus used to elicit the response is about 30 ms long. This stimulus duration is considerably longer than the attack time in most (but not all) digital hearing aids, thus allowing the compression circuits to stabilize. For hearing aids with very slow compression, the child may have lower audibility for connected speech than he/she does for the isolated speech sounds used within HearLab.

Cortical testing also has one other major advantage in contrast with ABR. The electrical events we are measuring are much larger and closer to our electrodes. On page three of his, “New Handbook of Auditory Evoked Responses,” James W. Hall discusses the size (voltage) of the various test data: ABR, Cortical (Auditory Late Responses), etc. He says, “Activity arising from the higher regions of the auditory system (the cerebral cortex) involves hundreds of thousands, perhaps millions of brain cells. The electrodes are also relatively close to the sources of this activity. Therefore, these responses tend to be somewhat larger in size (amplitude), on the order of 5 to 10  $\mu$ V. In contrast, activity generated by the ear, auditory nerve and brainstem, which involves fewer neural units and may arise at a further distance from the electrodes, may be extremely small, on the order of 0.10 to 0.5  $\mu$ V.”

Ok, changing the subject; let’s look at a couple of older patients.

### John Doe.

John Doe is a thirty-eight year old gentleman with a pending Workman’s Compensation case. He worked at a noisy fabrication plant for fourteen years. He says the noise exposure hurt his ears and he cannot hear. The “Workers Comp specialist” at

the plant sent him to North Shore Audiology. They gave John several hearing tests and fitted him with a pair of BTE hearing aids on trial.

John's first hearing test showed a sloping 65-85 dB hearing loss bilaterally for air conduction, the bone conduction scores were near 50 dB. He was referred to an ENT for the "conductive" component, but pneumo-otoscopy done with the microscope and tympanometry had been normal. The ENT ruled out middle-ear involvement.

North Shore Audiology gave John a second hearing test three months later and found about the same 65-85 dB hearing loss bilaterally for air conduction. The bone conduction thresholds (air-bone gap) observed during the first hearing test "disappeared" on the second audiometric evaluation. John and the audiologist talked about this. John said maybe he was responding to the vibration not the sound.

North Shore Audiology was uncomfortable with this case and wanted cortical tests to see how accurate the audiogram and hearing aid fitting were. They referred John to Dr. Judy Smith. John cooperated with the test. He had signed the release-of-information form and all other appropriate paperwork.

Dr. Judy talked with John. He gave her a copy of his latest hearing test done by North Shore Audiology. He said the hearing aids were working fine and he could hear well when he wore them. Without the hearing aids, he said, he could not hear. John had done his homework.

Dr. Judy started the "threshold" (CTE: cortical threshold estimate) tests with the Right ear using insert earphones. She observed good cortical responses at 65 dB SPL; she lowered the input level to 55 dB, then 45 dB and good responses were observed. She switched ears: Repeated the sequence: Once again good responses were observed.

At this stage John was becoming uncomfortable and he showed his irritation and he asked to "end the tests."

Dr. Judy told John that her test results were inconsistent with the hearing tests he had received at North Shore Audiology. She scheduled him for another visit. He never returned for the follow up visit.

Dr. Judy sent North Shore Audiology a report that said in effect, "My current tests indicate marked inconsistencies with your earlier hearing test, on the basis of these tests we cannot estimate John's *level of hearing loss*; however, because we obtained good CAEPs at 45 dB SPL bilaterally unaided, we believe his hearing is significantly better than the levels indicated by the behavioral audiogram."

North Shore Audiology forwarded Dr. Judy results to all interested parties and waited for the results of the additional studies but John never showed up for these studies.

### Tiffany

Tiffany is a sweet, very quiet, six year old girl living in a foster care home. She has been in several foster care families the last couple of years. She is in a special education classroom at school. She does not speak, she responds when asked to do things by teachers and her foster parents. The school audiologist, Margaret, gave her several hearing tests. Tiffany's responses were inconsistent; she responded at very high levels, e.g. 100 dB HTL. But, Margaret, the audiologist, wrote on the hearing tests, "I don't trust these values! We need additional tests."

Tiffany had been seen several times by a local pediatrician, Dr. Sanchez, who treated her for chronic otitis media with constant purulent drainage. Dr. Sanchez observed large perforations in both her ear drums.

Tiffany has been fitted with BTE hearing aids years before by another clinic, but Tiffany refused to wear them. Dr. Sanchez referred Tiffany to Dr. Judy Smith for a comprehensive evaluation.

Tiffany was a joy to work with and sat very quietly while Dr. Judy did the tests. Dr. Judy started with the "unaided" ACA test and she was delighted to see good cortical responses without a hearing aid at 65 dB SPL. Without question, Tiffany had some hearing loss due her middle ear problems but her hearing was much better than reported.

Dr. Judy switch to the CTE (cortical estimate assessment) and she presented "tones" to Tiffany using the bone vibrator. The responses were close to normal hearing levels.

This information was shared with:

- Dr. Sanchez, the Pediatrician, who referred Tiffany to an ENT to manage the middle-ear problem.
- The foster family.
- And Margaret, the school audiologist, who referred Tiffany to counseling.

It turns out that Tiffany was a severely abused child who lived in a “shell.” All reports about her being “deaf” were inaccurate. She needed considerable time in counseling. A year later, her speech and language skills were improving. Her ears are being closely monitored by the ENT, and the discharge has stopped. Quickly, with the love and support of teachers, counselors, and foster parents, she learned to come out of her protective “shell.” She was placed in a “normal” classroom.

Not all people have wonderful lives. Sweet Tiffany had had a terrible life; one that tears your guts out when you think about it. Tiffany was surviving the only way she knew how. She acted “deaf” even though she had pretty good hearing.

Tiffany was not able to respond accurately to the Margaret’s tests. Margaret had been told by the teachers that Tiffany could not “talk” so she assumed Tiffany had a severe hearing loss and believed incorrectly that Tiffany needed high power hearing aids.

The beauty of “cortical” tests is that while not all people can raise their hand when they hear a test signal the response can be seen with only passive cooperation from the patient. The cortical response correlates highly with perceived speech. We may prefer to use direct speech tests but these the patient to respond by repeating the words. But often the patient cannot do this. Tiffany could not do this when she was first seen by Margaret at school.

The story of HEARLab is more than a story about a new machine. *It is a story about bringing hearing to infants, babies and older people.* It is a beautiful story about helping children like Tiffany. Today, Tiffany can raise her hand when Margaret presents a pure tone and asks her to indicate when she hears the tone. But, there was a time when Tiffany could not raise her hand, so we turned to her “cortical” responses that said in effect to us, “I can hear! I can hear!”

A new chapter in the profession of Audiology has just opened. Major advances in research by

scientists around the world, and particularly in the USA, have shown us the importance of cortical responses in indicating not only the detection of sounds but the maturity of the auditory system in the cortex. NAL have added to this research by focusing on the automated detection of responses to speech sounds in infants. All of this research has been brought together into modern computer technology and hardware. Frye Electronics Inc. have produced this as an easy-to-use, clinically practical, reasonably priced, machine that can measure and analyze evoked cortical responses. Now the fun begins! We have the opportunity to do a better, more certain, job of bringing hearing to infants and people who have problems with responding in regular auditory testing.

The authors predict this new technology will generate so much excitement that it will not be long before you see audiologists and their little patients on many of the most watched TV talk shows.

NOTE: Lyndal intends to edit the following information and add as an Appendix to the final version of the user manual (Initially prepared for report of clinical evaluation by LC):

## Appendix A: Practical aspects of CAEP testing with infants

The HEARLab system has been designed to make objective audiological assessment as easy and efficient as possible. However, testing young children, regardless of the hardware and software employed, presents practical challenges.

The application of CAEPs to a pediatric population may be relatively new to mainstream clinical practice, however, the general techniques and strategies used in other areas of pediatric audiology are still highly relevant. Experienced clinicians will be well aware of how to best manage the test environment, and will have developed many of their own solutions to overcoming the issues that inevitably arise when working with infants.

The clinical validation trials of the new HEARLab system involved repeated CAEP measures, conducted in a controlled and systematic way. This provided a valuable opportunity to investigate different approaches and test techniques, and to consider their relative merits, without the usual restrictions of a routine clinical assessment appointment, in which a diagnostic outcome must be achieved within a limited time frame.

Some general suggestions, based on observations made during the study, are summarized in this Appendix. It is hoped that this information may provide useful guidance, particularly for clinicians with less experience in pediatric audiology, or those who are new to using electrophysiological assessment techniques with young children.

### Before the appointment

- Prior to the appointment, provide parents/care giver with information (written and verbal) about the procedure. This will reduce the time spent in explanation at the assessment.
- When arranging the appointment, ask about the child's routines. Try to book the test at a time of day when the child is likely to be in a "good" mood, and less likely to be overtired and irritable. Allow plenty of time so that appointment is not rushed, and it is possible to take breaks if needed.
- Check whether the parent/care giver intends to bring sibling/s to the appointment. If it is necessary for siblings to attend, make sure there will be suitable activities/supervision away from the test room. The parent should be free to focus their attention on the child having the test.
- Ask the parent/care giver to bring food, drinks, or dummies ("pacifiers") for the child, to the appointment. Some favorite toys, that are suitable as quiet distracters, can also be useful in making the child feel more secure in the test environment. DVDs that the child enjoys can also provide familiarity and useful distraction.
- Suggest that the child be dressed for the assessment in layers of clothing that can be easily removed. Electrode contact can be compromised if the child becomes overheated and "sweaty" and it may be necessary to remove clothing to cool them down. It is better not to have to pull clothes over the child's head once they are "wired up".
- Ask parents/care giver to ring and postpone the appointment if their child is unwell, particularly if the child has a temperature. A restless and irritable state is not conducive to quality recordings.
- Call the parent/care giver to confirm the appointment the day before, and take the opportunity to check whether they have any questions or concerns they would like to discuss.

### Test environment

- Make the test environment "child friendly". For example, decorate the test booth and surrounding areas using items such as mobiles, displays of soft toys (out of the child's reach), and fabric motifs. Avoid hard reflective objects that will cause sound reflections. Minimize technical "clutter". Keep wires out of view and laboratory supplies in drawers. Children, particularly if they have undergone medical treatment or hospitalization in the past, may associate such items with unpleasant procedures.
- Keep the test area clean and tidy. A plastic backed 'Draped' sheet (available from medical suppliers) is a useful surface for arranging preparation materials, and for wrapping used electrodes, cotton tips etc. afterwards for disposal.

- Provide a chair that is as large enough for the child to sit comfortably, either on their parent's lap or beside them, during testing. Some children become irritable if they feel overly restrained or restricted in their movements. Where possible, try to let them settle into a position which they prefer. A recliner chair works well as it can be used for adult testing as well.
- Use washable covers on the chair (eg, bath toweling) and change between assessments to maintain hygiene. This makes "dribbles" and food spills easier to contain and reduces parents inclination to perform immediate "clean ups", which can disrupt the testing. Have tissues or baby wipes at hand if needed.
- Have a container on hand to collect items that require cleaning, according to infection control guidelines (eg, toys that have been in the child's mouth).
- Some younger infants may be comfortable in a rocker/"Fraser chair", but don't rock the baby during recordings. "Bounces" can be evident in recordings and rocking can make a child sleepy.
- Fluorescent lighting can cause problems of electrical interference. Incandescent lighting should be used in preference. As well as providing a technical advantage, incandescent lamps can create a pleasant, relaxed ambience for children and parents. Novelty lamps (eg, artificial fish tanks, "lava" lamps), as well as providing illumination, can provide the child with visual distraction.
- It is important that the tester is able to monitor the test environment and the baby's state throughout the test. A strategically placed video camera can be extremely helpful if the arrangement of the test booth makes it difficult to maintain a clear view. A video camera that works well in low light is recommended.
- Where the tester is in a separate observation room, an audio monitor is essential in monitoring the ambient noise level in the test environment, to ensure consistent stimulus delivery, and is also useful in communicating with the distracter.

### Preparation for testing

- Children generally have a short attention span, and their mood and state can change quickly. Have all test equipment switched on, checked and calibrated before the child arrives. Have the recording system software open and ready on the impedance check screen to avoid unnecessary delays.
- If testing is with hearing aids on, change the batteries and check the devices on arrival. Having another staff member do this while you are interviewing the parent, this will minimize delay in commencing testing.
- Ensure that the parent understands what is involved in the test. The child is more likely to be relaxed and cooperative during the assessment if their parent is confident and relaxed about what is happening.
- Make the parent comfortable. Providing a hot drink or glass of water can help put parents at ease. It is a good idea to have a safe place to put a drink beside a parent so that it cannot be knocked onto baby or electrical equipment.
- Ensure the parent feels in control of the situation. Seek their advice about the child's preferences, and the best strategies for preparing them for testing. Respect their opinion and follow their suggestions.
- Try to build some rapport with the child. A little physical interaction with the child while you are interviewing the parent (eg, patting or stroking their arm or head) can be useful in gauging how they will react to the preparation for electrode sites, and may possibly help the child accept it more readily.
- Make sure the child's physical needs (eg, diaper changing) are attended to before starting preparation for the electrode placement.
- Have any items that might be needed (eg, bottles, food, toys) close at hand, in order to minimize noise and disruption during testing. Check with parents to see if bottles need warming or food needs preparation before you start.
- Attempt otoscopy and tympanometry first if indicated, but don't persevere if it causes the child to become too active or distressed.

- Ask parents to switch off mobile 'phones or pagers as these may cause distraction to the child if they ring during testing, and may also be a potential source of electrical interference.

### Preparation of electrode sites

- Attaching the electrodes is potentially the most challenging part of the test procedure. Approach the preparation confidently but not too forcefully. Smile, and talk to the child reassuringly.
- Start the preparation in a position where the child is comfortable and not overly restrained. For example, try starting while an older infant is playing on the floor, or at a child's table and chair.
- Try not to physically "stand over" the child while doing skin preparation. Working from behind the child may be a good option. For your own health and safety, try to maintain a posture that is ergonomic and doesn't place strain on your back or neck. Sitting on the floor beside baby whilst chatting to Mom or Dad and gently rubbing the skin can be a very non-threatening way to get the skin prepared.
- Electrode sites are generally prepared by abrading with a cotton applicator 'bud' and a medical gel intended for the purpose. Rub firmly and vigorously enough to cause a slight redness on the skin surface, but not so hard that the child becomes obviously distressed by the sensation. Rubbing gently, but firmly, back and forth works better than "dabbing" at the skin. Rub on the back of Mom or Dad's hand first so they know what it feels like.
- Work as quickly as possible and minimize the number of physical contacts with the child. Don't fuss or "overdo" it, but be mindful that it is better to prepare skin thoroughly than to have to repeat the whole process.
- If the child needs reassurance about the preparation, modeling the procedure (eg, by rubbing the forehead of the parent or a doll with a cotton bud, and sticking on an electrode) can be helpful. Try letting an older child have a "turn" at putting an electrode on a toy or on their parent.
- Some children will be reassured by watching the preparation in a mirror, but this may make others more apprehensive.
- Television can be a good distraction during electrode placement. Use a range of children's DVDs with lots of color and movement. If the child becomes interested, the DVD can be left playing (with the sound muted) when testing starts. This is the time to use your noisy, fun toys, before the real testing begins! Make sure you put these out of sight before you start.
- Wherever possible have a trained distracter (in addition to the parent), to interact with the child during electrode placement, as well as during testing. Toys that involve some fine motor manipulation (eg, block stacking, button pressing) can help keep hands away from the electrode sites.
- Cleaning skin with an isopropyl alcohol prep swab after abrading is sometimes recommended, and may improve contact, but it can make the electrode stick very firmly and make it difficult to remove. It can also feel "stingy" – try it on yourself if you don't believe this! Preparation with an alcohol wipe is not needed and is not recommended for the delicate skin of infants.

### Optimizing and maintaining electrode contact

- Use a liberal amount of electrode paste under the vertex electrode even if a disposable electrode, that already contains conductive gel, is used.
- If using disposable electrodes, a spot of double sided tape (the type used for retaining hearing aids) on the underside of the plastic tab of the electrode stud, can give a firmer hold, particularly for mastoid or forehead sites (ie, where the skin is free of hair).
- A headband is very helpful in keeping the electrodes in place, particularly at the vertex, but some children are less accepting of wearing a headband than others.
- To make wearing a headband more appealing to the child, choose colorful, soft and stretchy materials. Give older children a choice of colors or designs (eg, have a selection of different mo-

tifs sewn on a selection of headbands). Having a choice of “girls” or “boys” styles can be important to the child, and sometimes also to the parent. Use fabrics that are easy to wash and dry after use.

- Dividing the top of the headband before use (by cutting a slit a few inches long across its centre) allows a section of fabric to be stretched forward to hold the forehead electrode in place.
- Passing the leads under the headband can help reduce pulling and strain on the electrode site during the test.
- Elastic bandage, particularly of material that allows the ends to adhere without pins or tape (eg, “peg” bandage), can be a reasonable alternative, but tends to be more “fiddly” to put on than a headband. If an inexpensive type is chosen it can also be disposed of after use which can be an advantage.
- Micropore tape (either on its own or with a headband) is appropriate for keeping re-usable type electrodes attached.
- Once the electrodes are attached, try to drape the leads behind the child, avoiding contact with the child’s face or neck. If the child can feel them, they will be more inclined to pull at them. Try to keep the leads away from clothing (eg, don’t let them become tangled in bibs or collars).
- Loosely taping the leads to the back of the child’s clothing (using micropore tape) may be helpful, but ensure they are not taped so tightly that the electrode leads are pulled off the head if the child suddenly leans forward.
- Make sure that if the parent is holding the child, that the electrode leads are not cramped or pulled under the parent’s arm. Try directing the leads up and over the parent’s shoulder
- Avoid the child leaning back onto the electrode leads, or making sudden large movements, such as lunging forward. Strategic use of distraction toys can help in this respect.
- If the child starts to touch the leads or electrodes don’t over-react (eg, grab suddenly at the child’s hands). In preference, try to distract

the child by offering them an alternative item to play with.

- Once the electrodes are in place, avoid touching them unless really necessary (ie, they are obviously slipping/becoming unstuck). Drawing child’s attention to them will often result in renewed efforts to remove them.
- Don’t let the child overheat. This can result in electrodes lifting and the reject rate increasing. If the child gets very restless it can be better to suspend testing than let it proceed until they are “hot and bothered”.

### **Distraction techniques**

- The distracter is best seated in a comfortable position at, or below, the child’s eye level. Care must be taken to maintain an appropriate position in relation to the speaker if the stimulus is presented free-field.
- Have a wide selection of age appropriate toys that are not too noisy. Keep toys and other distraction aids in easy reach, to minimize noise and disruption as the test proceeds. Choose toys that can be cleaned according to infection control procedures. Toys that can’t be cleaned (eg, soft toys) should be kept out of the child’s reach.
- For very young infants, the main aim of distraction is to keep them alert and awake (they do not have the motor skills to pull at the leads or electrodes). Mobiles, hand and finger puppets are all useful items. Visual novelties (eg, toys with lights and motion) can be excellent. Some mechanized toys are too noisy to use while the testing is in progress, but can be good to use during breaks, in order to regain a child’s interest and increase alertness.
- Toys that are used for VROA distraction are generally suitable for children in the 7- 24 month age group. Examples include; stacking plastic rings or cups, farm animals, large counting and threading beads, puzzles, colorful teething rings and so on. Items that keep hands occupied are ideal for children old enough to manage them.
- For younger children or those who are not developmentally ready to “play” with items,

toys with texture (eg, spiky plastic balls, plastic animals etc) can be interesting for the child to touch or mouth (make sure you put them in the “washing” container after use).

- Action toys (eg, water-wheels, small spinning tops, “pecking” birds, “wobbly” animals, clear plastic balls that contain moving toys) can be useful as long as they are not too noisy. If children are allowed to hold the items they should not contain small parts that may be a choking hazard, and they must be easy to clean. Watch that water-filled toys don’t leak.
- For older infants (around 24 months and over) try coloring-in books with big colorful crayons, play-dough (if past eating it, or well supervised), paper with stickers or self-inking stamps.
- Books can be good for children of all ages. Heavy cardboard books of various shapes, or with flaps/pop-up features, can provide “hands on” activity. Books made of plastic (ie, intended for bath time) can be ideal for very young children as they are easy to clean if mouthed.
- Almost every child enjoys watching bubbles being blown. The small bottles used for parties are inexpensive and easy to use. Avoid “sticky” bubbles that are designed not to burst. They tend to leave messy residue in the test environment.
- Eating and drinking are excellent distracters. Good choices include baby bottles or infant sipping cups, and soft foods such as banana, custard, fruit gel, or sultanas. Avoid hard foods (eg, crunchy crackers) or large pieces of food of that require a lot of chewing, as the resulting noise and jaw movements can affect recordings.
- Breastfeeding is good for calming infants, but often can induce sleep. If the baby must feed during the assessment, watch very carefully and rouse the child gently if they begin to doze off, or appear their eyes start to appear “unfocussed”. Be prepared to pause testing if the child’s state becomes inappropriate. Sometimes a short break to have a feed can give baby a boost to keep them going for a bit more testing.
- Avoid distraction activities that are too stimulating or that encourage increased vocalization, for example, physically vigorous play, or games/gestures that encourage the child to answer questions or name objects. Parents may sometimes need some guidance about activities that are inappropriate in this respect.
- If the child is content and quiet it can be best for the distracter to sit quietly or withdraw and leave them to their own devices. If the child is unsettled sometimes it can help for the distracter to get right out of their view and let the parent try to settle the child before proceeding.
- Try to end the test on a “happy note”, rather than persisting until the child (and potentially the parent) is distressed. This is especially important if the child will have to attend on another occasion.

## Appendix B: Translation of research to HEARLab, a clinically practical instrument.

Research finding or practical problem addressed	Clinical implementation or solution
Cortical response shapes vary widely from person to person	An automated statistical detection method that does not require any apriori assumptions about the “normal” response shape, that combines information from different parts of the response, and that shows the probability of the response, being evoked by the stimulus.
Response latency varies with the maturity of the auditory system.	Normative data built into the software display the range of latencies expected for babies (or children or adults) for auditor system maturity appropriate to the age of the person being tested.
Inadequate averaging, or excessive movement by the children, creates variability in the age waveform that can mask the underlying cortical response.	Residual noise in the waveform is continuously calculated, and traffic light indicators show when the residual noise is sufficiently low that the absence of a cortical response can be interpreted as indicating inadequate sensation level.
Predicting audibility of speech sounds from pure tones measurements of threshold and hearing aid performance is very complex and error prone.	Use speech sounds as a stimuli, and automatically correct for the response of the loudspeaker and the room transmission characteristics.
ABR is best measured when the baby is asleep, but babies are not always asleep when needed. Cortical responses are best measured when the baby is awake, making the techniques complementary.	Incorporation of pure tones, delivered through insert earphones, enable hearing thresholds to be estimated for an awake baby (or adult) through measurement of cortical response to tonal stimuli, still with automatic statistical detection of responses.
Electrical interference from the room adds to measurement noise and can make it slow or impossible to measure a valid response.	Miniature pre-amplifiers on the active and reference electrode connectors greatly reduce capacitive pickup of interference within the electrode leads.



