AUDITORY BRAINSTEM RESPONSE (ABR) PROTOCOL

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BC Early Hearing Program

A service of BC Children's Hospital
and the Provincial Health Services Authority

BRITISH COLUMBIA EARLY HEARING PROGRAM: AUDITORY BRAINSTEM RESPONSE PROTOCOL

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AUDITORY BRAINSTEM RESPONSE PROTOCOL

COMMON ACRONYMS

AABR	Automatic ABR
ABR	Auditory Brainstem Response
AC	Air Conduction
ANSD	Auditory Neuropathy Spectrum Disorder
AR	Acoustic Reflex
BC	Bone Conduction
BCCH	BC Children's Hospital
BCEHP	British Columbia Early Hearing Program
BERT	British Columbia Early Hearing Resource Tool
BEST	British Columbia Early Hearing Surveillance Tool
CAEP	Cortical Auditory Evoked Potential
CC	Condensation Click
cCMV	Congenital Cytomegalovirus
CHL	Conductive Hearing Loss
CM	Cochlear Microphonic
CMRR	Common-Mode Rejection Ratio
CNE	Could Not Evaluate
CQI	Continuous Quality Improvement
DP	Distortion Product
DPOAE	Distortion Product Otoacoustic Emission
EEG	Electroencephalogram
EHDI	Early Hearing Detection and Intervention
eHL	Estimated Behavioural Hearing Level
EM	Electromagnetic
ENT	Ear, Nose and Throat Specialist
FFR	Frequency Following Response
IHC	Inner Hair Cell
IHS	Intelligent Hearing Systems
nHL	Normal Hearing Level
NHS	Newborn Hearing Screening
NR	No Response
OAE	Otocoustic Emissions
OHC	Outer Hair Cell
PAMR	Post-Auricular Muscle Response (or Reflex)
PHL	Permanent Hearing Loss
PSA	Program Support Audiologist
RC	Rarefaction Click
RECD	Real-Ear-to-Coupler-Difference
RN	Residual Noise
RP	Response Present
SII	Speech Intelligibility Index
SNHL	Sensorineural Hearing Loss
SNR	Signal-to-Noise Ratio
SP	Cochlear Summating Potential
VRA	Visual Reinforcement Audiometry

PREFACE

Since the last full revision (2012), the BCEHP Auditory Brainstem Response (ABR) protocols have undergone incremental revisions. This 2022 document includes those changes, as well as several new changes. This BCEHP ABR audiometry protocol document replaces and overrides all previous BCEHP documentation relating to ABR-based audiometry issued before November 2022.

In addition to incorporating changes in ABR audiometry protocols, the current document also represents a substantial change in its format compared to the 2012 document, with the hope that users of this new document will find it easy to follow. Additionally, in later subsections (3, 4 & 5), this new protocol document now provides many diagrams that help explain the protocols.

Each subsection begins with a brief summary (in a box) that provides an indication of both the topic as well as some key points that follow in the detailed paragraph(s). The summary paragraphs, however, are not intended to replace or fully summarize these details.

ABR Audiologists looking for an overview of the procedures required by these revised protocols will find these summarized in Section 4.4 Mandatory and Discretional Procedures for Determining Hearing Status. An ABR Audiometry Quick Reference Guide for use during testing is also available. ABR Audiologists, however, will still have to review the full document to get complete details.

In this document, most links are available publicly and may be accessed by clicking on the blue links. Orange links are only available to clinicians with access to PHSA's internal website.

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1 BC EARLY HEARING PROGRAM (BCEHP) SERVICE CONTEXT

1.1 WHAT IS BCEHP ABR AUDIOMETRY?

BCEHP ABR audiometry (henceforth "ABR audiometry") is a detailed, multi-component assessment process for confirmation and characterization of hearing disorders that is authorized by BCEHP and provided through public entities such as public health audiology and BC Children's Hospital (BCCH). Its core components include ear-specific, frequency-specific, air- and bone-conduction threshold estimation and evaluation of auditory pathway function by ABR. Additional techniques may include click-evoked cochlear and neural potentials, tympanometry, distortion product otoacoustic emissions (DPOAE), acoustic reflexes and measurement of real-ear-to-coupler-differences (RECD).

In most cases, the ABR will be a child's first audiometric assessment. Complete ABR testing usually requires only a single session because the baby will be asleep and hearing will be rapidly found to be within normal limits. In other cases, such as those for which a hearing threshold elevation has been identified, additional sessions may be required to complete the assessment.

1.2 WHO CAN CONDUCT ABR AUDIOMETRY FOR BCEHP?

Only audiologists registered with the College of Speech and Hearing Health Professionals of BC (CSHBC) who are trained and authorized by BCEHP to conduct this protocol may provide ABR audiometry services with BCEHP funding. The BCEHP-certified ABR Audiologist must personally conduct the testing and interpret the results. In areas of the province where staff retention and/or access to services are limited, ABRs may be conducted via telehealth technology.

Only audiologists certified by the CSHBC *who are trained and authorized by BCEHP to conduct this protocol* may provide ABR audiometry services with BCEHP funding.

The rationale for this consists of several important points:

- This protocol is technically demanding and contains elements that may be outside the conventional experience of many pediatric audiologists.
- Specialized training is required to maximize understanding of, and to fulfill, a highly specific standard of care with many mandatory elements.
- For continuous quality improvement (CQI), audiologists who conduct ABR audiometry for BCEHP receive regular reviews with defined deliverables; this process requires explicit and regular exposure to the procedures required and their rationale.

The BCEHP-certified ABR Audiologist (henceforth "ABR Audiologist") must personally conduct the testing and interpret the results. At any given clinical encounter, the designated ABR Audiologist is responsible for both the performance of the testing and the interpretation and reporting of the results. These activities cannot be delegated. Audiology graduate students require experience with the type of testing provided through BCEHP within the context of a safe and appropriately supervised environment. Clinical educators may allow these students to participate in all or part of the assessment under their direct supervision

but must meet the requirements outlined in the "ABR Assessment and Graduate Student Participation Policy" (on BERT). The presence of any observer must not compromise the effectiveness, efficiency or appropriateness of any aspect of the audiologist's technical activities or interactions with the child and the family.

In areas of the province where staff retention and/or access to services are limited, ABRs may be conducted via telehealth technology. At the time of writing this document, telehealth-ABR assessment is offered in the Northern Health Authority and the Interior Health Authority (Hatton, Rowlandson, Beers & Small, 2019).

Audiologists outside BCEHP may choose to adopt BCEHP procedures; however, their activities do not qualify for BCEHP funding because they are not registered as BCEHP providers, have not received the mandatory training, are not subject to ongoing quality improvement and assurance reviews, and their activities are neither budgeted nor verifiable by BCEHP. Accordingly, ABR audiometry must be provided by BCEHP-certified ABR Audiologists in order for infants and young children to quality for any other BCEHP services.

1.3 CONTINUOUS QUALITY IMPROVEMENT (CQI)

BCEHP is required to implement quality assurance and quality management on an ongoing basis to maintain high quality of care and for accountability. This is being done through a CQI program that targets all major service components, including ABR audiometry. The ABR-CQI process is delivered by a panel of experts, the "ABR-CQI Panel", and includes training and clinical decision support, as well as performance monitoring (ongoing regular review, low-caseload review, non-approved-provider review) and adverse event-driven review.

The CQI components are directed towards enabling and supporting ABR Audiologists to deliver the highest possible quality of care to children and their families. The key indices of quality are effectiveness, equity and efficiency, which are reflected in the accuracy, completeness, timeliness and consistency of assessments. Test timeliness, accuracy, efficiency, protocol adherence and use of supports and referrals are current areas of focus. See the BCEHP ABR-CQI Process (on BERT) document for process specifics.

1.4 ROLE OF BCEHP PROGRAM SUPPORT AUDIOLOGISTS (PSA)

BCEHP provides ABR consultation and referral services, protocol support and clinical decision support to ABR Audiologists.

BCEHP provides clinical support to ABR Audiologists providing BCEHP services. This support has been provided by Program Support Audiologist(s) at BCCH since the inception of BCEHP in 2008. The PSA(s) are best reached using their shared ABR support email. PSA(s) provide support for ABR matters relating to this protocol. This support includes but is not limited to:

- clinical decision support to ABR Audiologists
- ABR consultation and referral services
- protocol development and support
- research, evidence review and outcome measurement

- under the direction of the BCEHP ABR-CQI Panel, various aspects of quality assurance and CQI, including ABR Audiologist training (initial, refresher and advanced), BCEHP practice reviews and adverse event-driven reviews

1.5 BCEHP ABR TRAINING

BCEHP provides training for ABR Audiologists. Typically, BCEHP training for ABR audiometry involves initial training at BCCH, followed by additional training at the local ABR site where the clinician will be conducting the testing. Training beyond this is determined on a case-by-case basis. Refresher training may be requested by any ABR Audiologist at any time, but is required after a period of ABR inactivity spanning greater than 6 months.

The need for initial ABR audiometry training is identified by Regional Coordinators and reported to the PSA(s) as they arise. If approved, the PSA(s) will determine the priority of the training and arrange its scheduling with the trainee. Typically, training for ABR audiometry involves initial training at BCCH, followed by additional training at the local ABR site where the ABR Audiologist will be conducting the testing. Training is usually a 2- or 3-day hands-on course, involving technical tutorials, clinical observation, familiarization with instrumentation, hands-on testing of babies, in-depth discussion of results and chart reviews. Prior to the trainee's release from this process, the trainee's clinical results in the field will be monitored until procedures and interpretations are considered satisfactory by the PSA(s). This initial monitoring process may typically involve 15-25 new cases. It is expected that trainees will have ABR audiometry incorporated into their clinical practice within 2 weeks of completing the hands-on training component.

Refresher training may be requested by any ABR Audiologist at any time but is required after a period of ABR inactivity spanning greater than 6 months. If an ABR Audiologist authorized for ABR audiometry does not carry out ABR assessments for a period of 6 months or more, the Regional Coordinator must advise the PSA(s) of the lapse in practice. The PSA(s) will arrange for refresher training. Clinical decision support and performance monitoring by a PSA may also be recommended.

In addition to the initial and refresher training discussed above, all ABR Audiologists are required to participate in an ongoing CQI process, engage in program support resources, participate in biennial ABR Workshop learning opportunities, and ideally perform a minimum of 24 ABR assessments each year.

Note that ABR Audiologists are encouraged to seek support, monitoring or refresher training of their own volition at any time, and certainly for any case where ABR audiometry results are challenging to interpret or incomplete.

1.6 ABR AUDIOMETRY PROTOCOL SUPPORT BY PSA(S)

ABR Audiologists who have any questions or concern about any aspect of this ABR protocol are recommended to contact the PSA(s) at BCCH to discuss the matter. This is also a mechanism for protocol clarification and improvement through the BCEHP CQI panel.

This protocol includes several substantial changes from the 2012 protocol. ABR Audiologists providing ABR services who have any questions or concerns about any aspect of this ABR protocol are recommended to contact the PSA(s) to discuss the matter. While peer-to-peer consultation is sometimes helpful, consultation with a PSA is strongly encouraged. By discussion with audiologists in the field, the PSA is able to develop awareness of protocol areas that may require clarification or modification. This is also a mechanism for

protocol clarification and improvement through the BCEHP ABR-CQI panel. All interactions with PSA(s) are confidential. For unusual or complicated ABR cases or concepts, the PSA(s) may request additional consultation from UBC experts. This will also be confidential.

1.7 CLINICAL DECISION SUPPORT BY PSA(S) OR REFERRAL

ABR Audiologists are encouraged to consult the PSA(s) if they wish to discuss ABR procedure, interpretation or next steps for any specific child. Real-time support during testing may be feasible to some extent, depending on the availability of the PSA(s). Email contact is preferred. Records sent by email or fax for review must be de-identified. Audiologists may also elect to refer a baby to BCCH for ABR. Referrals may be made in response to case complexity, difficulty obtaining a satisfactory test, upon parental request or to secure testing under sedation. The PSA at BCCH may elect to try unsedated testing first, after review and discussion with the referring audiologist.

Even the most skilled ABR Audiologists may be confronted by difficult challenges of procedure, interpretation or next-step planning. Although the ABR audiometry protocol has been developed from existing evidence, BCEHP practice and expert consultation, there remain aspects of ABR audiometry for which the underlying scientific evidence is lacking or for which expert consensus is incomplete. In many respects, ABR testing is based on both research evidence and clinical experience. Clinical decision support from PSAs is not about what is right or wrong or about evaluating the ABR Audiologist; it is about information and knowledge transfer between clinicians and how to do the best job of service delivery for infants and families.

Challenges often arise in situations that involve, for example, an ANSD component or mixed conductive/cochlear hearing losses. Such cases should be referred promptly to a PSA if there is any difficulty with procedure or uncertainty in interpretation. In some cases, problems with repeated testing and referrals may be avoided easily by discussion of initial results with a PSA.

ABR clinical decision support may involve answering questions about procedure, protocol or interpretation, discussing concerns or challenges, commenting on next steps in a current case or arranging referrals for further ABR testing at BCCH. If consultation with a PSA is pursued, a copy of the correspondence with the PSA, including recommendations and ABR interpretations, must be retained in the clinical chart. Every effort is made by BCEHP to provide real-time support. While real-time support is often possible, it is dependent on the PSA's schedule. BCEHP endeavours to ensure that at least one PSA is available at all times during the work week. Every effort is made to provide prompt feedback; response from a PSA within 48 hours is targeted with best efforts.

Clinical records for review may be faxed or sent as email attachments. The preferred contact method is the shared ABR support email. To protect patient/client/family confidentiality, all records must be de-identified and code referenced using the unique 10-digit "BCEHP number" that is generated by the BEST data system. This data system is accessible only to those hearing health professionals who have approved access to the data system and are involved in the direct care of the infant. All records must contain this unique ID to facilitate PSA record-keeping and referencing. Emails may only be sent from health authority emails.

Audiologists may sometimes wish to initiate a consultative referral for ABR audiometry at BCCH. Reasons for this may include inconsistent results, records that are difficult to interpret or persistent challenges achieving a satisfactory test. Alternatively, the ABR Audiologist may wish to procure testing under sedation.

1.8 PROTOCOL ADHERENCE IS A REQUIREMENT

This protocol replaces and overrides all previous BCEHP documentation relating to ABR-based audiometry issued before November 2022.

All ABR assessments must be conducted in adherence to this protocol; such adherence is an expectation for continued authorization to provide ABR audiometry services for BCEHP. The protocol includes three classes of procedure: (i) mandatory, (ii) mandatory in specific circumstances (conditional mandatory) and (iii) discretional. Discretional procedures can be carried out provided they do not compromise accuracy or timeliness of the mandatory components. They should only be carried out after completing all mandatory components. See Section 4.4 for details.

The ABR audiometry protocol is based on extensive review of published evidence (including new evidence published since the preceding 2012 BCEHP ABR Assessment Protocol), experience since the inception of BCEHP, as well as experience from programs worldwide. Many data sources are evaluated on an ongoing basis by the CQI Panel and the PSAs. This process has resulted (and will in the future) in BCEHP stipulating procedures that differ from opinions of some individuals or the conclusion of specific (and often isolated) papers published in both peer-reviewed and non-reviewed literature. Nevertheless, raising an issue regarding the ABR audiometry protocol may trigger discussion, re-examination of evidence and a consensus development process, prior to province-wide or region-specific protocol change, if the case for change is substantiated. BCEHP will continue to evaluate research considering new stimuli (e.g., narrowband "chirps") and other procedures (e.g., auditory steady-state responses), some of which are currently being carried out at UBC and BCCH. When supported by sufficient data *and* clinical experience, BCEHP will consider changes to this protocol.

Experience indicates that if significant deficiencies in the quality of care occur, they are usually associated with a clinical error or omission related to protocol non-adherence. Therefore, program due diligence requires that protocol adherence be specified, facilitated and monitored.

1.9 LEGITIMATE DEPARTURE FROM PROTOCOL

Case-specific situations sometimes arise that legitimately justify departure from mandatory protocol elements. It is expected that departures will occur occasionally, not routinely. Such departures must be noted in the clinical record (i.e., typically on the ABR recording sheet) with a brief explanation. All such notes must be accessible to BCEHP ABR-CQI reviews.

If ABR results are substantively non-adherent to the ABR audiometry protocol such that any mandatory elements are not obtained (specified in Section 4.4), results must be sent to the PSA for consultation before further audiologic services from BCEHP will be considered.

BCEHP reserves the right to review documentation and clinical records involving any departures from this protocol. Such departures are typically noted on the ABR recording sheet (Appendix ABR1). If the departure is documented and reasonable, then the departure would be considered as a justifiable non-adherence event.

1.10 CHANGES TO THE ABR AUDIOMETRY PROTOCOL

Prior approval by the BCEHP CQI panel is required in order to substantively change any element of this protocol. Program-wide changes can occur only through a directive from the BCEHP CQI panel and/or a systematic process that may include survey of audiologists' experiences or concerns, evidence review and recommendation by a PSA.

Systematic changes to the ABR audiometry protocol locally or regionally can only be authorized by the ABR-CQI Panel. Such changes may be prompted by regional or local characteristics or challenges, sometimes affecting specific groups of service recipients. The process for systematic change is led by a Regional Coordinator. It includes documentation of the proposed change, its rationale and anticipated impact, followed by submission to the ABR-CQI Panel; this may be followed by evaluation, discussion, modification and explicit authorization.

A different type of protocol change process arises if any individual ABR Audiologist has a significant concern regarding a specific protocol element. The first step is to discuss the issue with a PSA, to ensure that the element and its rationale are fully understood. This raising of issues is welcomed as a way to resolve misconceptions or miscommunications and, potentially, to facilitate protocol improvement.

The negative effects of not addressing concerns about the ABR audiometry protocol include misunderstandings, clinical errors and opinion-driven non-adherence to protocol. Variations in viewpoint are inevitable, but the raising of concerns gives an opportunity to re-examine procedures and change them where change is justified, or at least render a mandatory element discretional if the evidence for it is determined to be limited or inadequate. Engaged professionals are a major resource for protocol evolution and improvement.

1.11 TARGET POPULATION

Candidates for ABR audiometry include all babies who are British Columbia residents who bypass or do not pass newborn hearing screening (Otocoustic Emissions (OAE)- or AABR-based) or passed screening but have risk factors for delayed/late onset hearing loss, as well as children younger than 5 years of age whose hearing is not testable behaviourally with acceptable accuracy.

The target population for ABR audiometry includes all British Columbia-resident babies who:

- fail the BCEHP Newborn Hearing Screening (NHS) protocol or
- bypass[1] hearing screening in accordance with NHS protocol or
- pass screening but are referred for ABR audiometry due to a risk factor for hearing loss in accordance with NHS protocol or
- are under 5 years of age but are unable to complete behavioural audiological assessment with acceptable accuracy to sufficiently inform hearing aid fitting or clinical next steps

[1] Babies bypass NHS if physically they cannot be screened, if their likelihood of permanent hearing loss is high (e.g., congenital bilateral aural atresia) or if there are other factors that require urgent testing (e.g., meningitis).

1.12 TARGET DISORDERS

The BCEHP target disorder set includes: (i) permanent hearing loss (PHL) of 30 dB HL or more at 0.5, 1, 2 or 4 kHz in any ear, (ii) ANSD and (iii) auditory brainstem pathway disorders that may be detectable using ABR techniques.

The BCEHP target disorder includes any permanent hearing loss (PHL) for which there is reasonable evidence that it will compromise auditory communication development and speech perception, in the absence of intervention. The normal minimum stimulus intensities specified in this protocol all equate to perceptual thresholds of about 25 dB HL, reflecting BCEHP-targeted hearing loss of 30 dB HL or more. Most PHL includes a loss of sensitivity to sound, as reflected in audiometric thresholds.

The target includes:

- PHL of 30 dB HL or greater at any frequency in the range 0.5 kHz to 4 kHz, in either ear
- auditory neuropathy spectrum disorder (ANSD)
- auditory brainstem pathway disorders that may be detectable using ABR techniques

The qualifier "permanent" encompasses most hearing losses caused by sensorineural dysfunction(s) of the cochlea and/or the brainstem auditory pathways, as well as conductive dysfunction(s) associated with structural differences of the ear that affect sound conduction through the external or middle ear structures.

It is considered appropriate to include children with unilateral PHL because many will have aidable PHL and are considered candidates for monaural amplification. In addition, children with unilateral PHL are at risk for bilateral PHL, and increased risk should the normal ear acquire a conductive disorder; such children require specific strategies to enhance hearing and/or communication development. Please refer to the BCEHP Amplification Protocol for eligibility for amplification in cases of unilateral hearing losses.

BCEHP target disorders include Auditory Neuropathy Spectrum Disorder (ANSD). ANSD is included in the target because it may be present in up to 10% of infants with sensorineural hearing loss (SNHL) and because, even if there is negligible loss of hearing sensitivity (i.e., minimal pure-tone threshold elevations by behavioural audiometry), there is likely to be a significant disorder of speech perception.

The BCEHP target hearing loss definition is more inclusive than that of many programs internationally, in that unilateral, mild and hearing losses limited to specific frequencies are included, as well as ANSD and certain retrocochlear disorders such as space-occupying or demyelinating lesions affecting the auditory brainstem neural pathways. BCEHP target disorders do not include hearing losses less than 30 dB HL or outside the range 0.5 – 4 kHz.

1.13 CONDUCTIVE HEARING LOSS

The ABR audiometry protocol is designed to determine the presence of conductive hearing loss (CHL) when thresholds are elevated. However, purely CHL identified by ABR is not a BCEHP target unless obviously or presumptively structural, such as in congenital atresia or if a syndrome associated with structural conductive anomalies is identified or suspected.

CHL that is not "permanent" is not a BCEHP target disorder. However, defining whether or not a CHL is permanent is not easy. It reflects duration of continuous presence of the hearing loss, given usual care by an otolaryngologist. But determination of how long, how constant and whether "usual care by an otolaryngologist" is forthcoming or effective is challenging. The simplest approach is to either identify cases that are classifiable as permanent or not and then cover other scenarios by making them discretional but guided by defined principles.

PRESUMED PERMANENT

First and foremost, the ABR Audiologist must demonstrate presence of hearing loss at specific frequencies and severity that fall within the target hearing loss range. If a sensorineural component is ruled out, primarily by bone-conduction ABR, the loss is deemed to be conductive. Absence or complete closure of the external auditory canal automatically confers permanence, but in all other cases, permanence of conductive loss must be presumed, based on guided principles. If a syndrome that is known to be associated with permanent conductive loss is already documented, the CHL may be presumed to be permanent. The same is true if a non-syndromic anomaly or external or middle-ear structure has been identified.

PRESUMED TEMPORARY

Where there is no sensorineural hearing loss (SNHL) (i.e., bone-conduction ABR is normal) and a relevant syndrome or anomaly is not suspected, classification of permanence is presumptive and is at the ABR Audiologist's discretion, based mainly on tympanometry and ABR-based thresholds. For example, if the tympanogram using an age-appropriate probe frequency is flat, air-conduction ABR thresholds are elevated with a range of about 40-70 dB nHL and corresponding bone-conduction ABR is normal, it is reasonable to infer that the loss is likely to be attributable to a transient middle-ear disorder. Of course, actual presence of middle-ear fluid usually can only be determined definitively by careful otoscopy by an experienced physician.

MEDICAL REFERRAL

The management of middle-ear disorders is a medical/surgical matter that should be evaluated and managed by a physician, as should the associated audiologic assessment. BCEHP is not a systemic replacement for BC's Medical Service Plan (MSP) system for pediatric hearing health care; rather, it is complementary to it. Given the common occurrence of middle-ear disorders in infants, routine inclusion of their audiologic management would overwhelm BCEHP resources and compromise the quality of care for those who have PHL. With discretional exception of minor conductive losses isolated at 0.5 kHz and accompanied by a flat tympanogram, detection of clinically significant hearing loss indicates referral to a physician. The criteria for and the timing of such referral are at the discretion of the audiologist. One view is that immediate referral of infants with isolated CHL is premature, given that watchful waiting is the usual course. It is also wasteful of valuable medical resources, with little tangible benefit to the child and family. One option is that if the CHL at 0.5 kHz is substantial and also includes a loss at 2 kHz, the infant should be re-tested after a waiting period to allow resolution of the loss. If evidence for middle-ear pathology has resolved on re-test, an arguably premature medical referral is avoided. In contrast, if the CHL is sustained, the more informed medical referral is fully justified.

The length of the wait period is discretional but should be in alignment with medical guidelines for management of otitis media (Rosenfeld et al., 2016). If the infant failed newborn screening then that failure could be considered the first detection of loss, which was then shown later to be conductive. If the initial ABR occurred at 8 weeks corrected age, then only a 4-week delay before re-testing could be sufficient to establish CHL presence over a 3-month period, consistent with medical guidelines for management of otitis media. On the other hand, a longer delay gives more time for disorder resolution, but may result in delayed referrals. For these reasons, the re-test interval is at the audiologist's discretion.

AUDIOLOGY-DRIVEN MONITORING

As stated previously, the management of middle-ear disorders is a medical/surgical matter that should be evaluated and managed by a physician, as should the associated audiologic assessment. While outside the scope of BCEHP, most public health audiology clinics discretionally choose to monitor these children audiologically, as per their local clinic/health authority policy. Periodic monitoring with tympanometry and otoacoustic emissions is common practice. Where feasible and is often the case, this audiology-initiated testing should be done in coordination with the child's medical management.

AMPLIFICATION

Note that children with long-term CHL exceeding 6 months in duration may be eligible for amplification on loan through the BCEHP Loaner Hearing Aid Policy when medical management is not available and/or the hearing loss permanency is not yet known. See the BCEHP Amplification Funding Policy for details regarding eligibility for BCEHP-funded equipment.

MIXED HEARING LOSS

Finally, as for the situation in which there is a conductive overlay on a SNHL, any CHL is a complicating variable that can decrease the accuracy of air-conduction ABR and complicate or prevent effective audiologic management of the infant. This is a longstanding challenge for all early hearing detection and intervention (EHDI) programs. The management process in the presence of conductive overlays is at the audiologist's discretion.

1.14 ABR AUDIOMETRY OBJECTIVES

In each ear, to detect and quantify hearing loss and, wherever feasible, to infer the site(s) of lesion(s). The overall assessment goes beyond audiometry itself and includes informational and counselling components that help families to become informed, engaged and empowered.

The main objectives of ABR are to:

a. determine the presence or absence of a target hearing loss

b. quantify hearing loss laterality (left, right, bilateral), component type(s) (SNHL, CHL, mixed, ANSD, retrocochlear), severity and configuration with sufficient accuracy and efficiency to inform and facilitate timely and appropriate provision of BCEHP intervention services elected by the family

c. achieve (a) and (b) by 3 months corrected age where feasible medically and

d. discuss test results with families in such a manner as to facilitate understanding, acceptance and positive engagement to the greatest extent feasible

Objective (d) reflects the fact that accurate and efficient ABR is ineffective unless it leads to prompt and appropriate action by the family. Therefore, laying the groundwork for successful intervention is considered a key component of ABR audiometry that is primarily the responsibility of the ABR Audiologist conducting the assessment.

1.15 AGE AT START OF INITIAL ABR AUDIOMETRY

The "initial ABR" is the first audiologic assessment for a young infant, typically following either referral from newborn hearing screening or screening bypass for babies at very high risk of PHL. Initial ABR testing may involve more than one test session. The first ABR session is targeted to occur between age 4 weeks and no later than age 8 weeks (corrected for prematurity, relative to a 40-week term).[2] For babies whose perinatal hospital stay extends beyond 44 weeks gestational age, ABR should be targeted to begin within 4 weeks of hospital discharge home.

Although Automatic ABR (AABR) screening can be carried out after 34 weeks gestational age, initial-ABR audiometry should *not* be initiated before 37 weeks gestational age (GA) because neurodevelopmental immaturity can cause ABR interpretive difficulty, inaccuracy and inefficiency. In addition, ABR audiometry within about a week of birth may be prone to errors associated with transient perinatal CHL due to unresolved debris or fluid in the external or middle ear. The 4-week target minimum ensures neurodevelopmental maturity and allows some time for transient external or middle-ear conditions to resolve, thereby increasing the accuracy and efficiency of ABR audiometry. Typically, the initial ABR audiometry appointment is scheduled to occur around 44 weeks. However, early testing may be requested by a treating physician as part of medical management, such as for the purpose of deciding whether to initiate antiviral therapy in babies with congenital Cytomegalovirus (cCMV). The 4-8-week target for scheduling the initial ABR assessment allows sufficient time to complete ABR audiometry by 3 months of age in cases where more than one assessment is required.

Assessment initiated by BCEHP is always conditional upon the recipient's medical condition being appropriate and stable. The timing specified above refers to the first ABR audiometry appointment attended after discharge from the hospital. If the baby is referred for ABR audiometry by a physician prior to discharge from the hospital, whether in natural sleep, under sedation or general anesthesia in the context of a medical/surgical procedure, compliance with the order is at the audiologist's discretion and is a regional policy matter. It is reasonable to alert the referring physician to the ABR audiometry protocol target and rationale, where feasible.

1.16 AGE AT "COMPLETE" INITIAL ABR AUDIOMETRY

Initial ABR audiometry is targeted to be completed by 3 months corrected age, at the latest. Widespread achievement of this objective is a high priority for BCEHP's CQI of ABR services. The PSA should be contacted if it is expected that ABR audiometry will not be completed by age 3 months (corrected) due to audiologic complexity.

The international performance benchmark is completion of the initial ABR audiometry assessment by 3 months corrected age, at the latest. A PSA must be contacted if it is expected that ABR audiometry will

[2] An infant is considered full term if they are born between 37 to 42 weeks gestational age. No corrections are typically applied if an infant is born full term. If an infant is born prior to 37 weeks (preterm), corrected age is calculated based on the expected date of delivery, which is 40 weeks.

not be completed within this timeline due to audiologic complexity. This timeline is typically necessary in order to begin intervention for PHL by the key benchmark of 6 months. Examples of "beginning intervention" include fitting of verified hearing aid(s) or first attendance at an appointment for communication development services.

Timely completion of ABR audiometry in turn depends on timely screening and referral. Because the majority of babies referred from screening will not have a target hearing loss, ABRs typically will be completed in one session, and the 3-month benchmark is achievable in most cases. However, when sensorineural hearing loss is present, and particularly if there is concurrent conductive loss, several appointments may be required to complete the ABR, and these must also fall inside the 3-month completion target. The 3-month benchmark most critically applies to these cases, not just to the majority of referrals who have hearing within normal limits. This means that the timing of screening referral and initial ABR assessment generally must take into account the delays inherent in booking one or even two follow-up ABR sessions.

Other important factors include the rapidly decreasing likelihood of accurate and complete testing as well as rapidly increasing costs as babies grow older. Babies younger than about 2 months of age sleep for long durations and are usually easy to test accurately and quickly by ABR audiometry. As babies get older, natural sleep becomes increasingly difficult. If PHL is present, several test sessions may be needed and cumulative delays compound the difficulty and cost of an adequate assessment. Testing under sedation is a limited and expensive option with finite associated risk and is rarely required for infants aged under 6 months.

1.17 SCREENING BYPASS IN INFANTS AT VERY HIGH RISK FOR PERMANENT HEARING LOSS

Babies bypass NHS if physically they cannot be screened, if their *a priori* likelihood of PHL is sufficiently large or if there are other factors such as pathogenic urgency.

There are several reasons why babies with specific indicators of very high PHL risk should bypass newborn screening and be routed directly to ABR audiometry. One basic principle is that screening becomes less and less appropriate the higher the *a priori* likelihood of PHL presence; current screening technology has substantial false-negative rates due to multiple sources of random error, and furthermore, AABR screening with broadband transient sounds (clicks or chirps) is not sensitive to hearing loss in restricted frequency regions of the cochlea. Another concern is that screening is a discrete event that can miss emergent or progressive PHL, especially in babies at substantial risk for deterioration in auditory system structure and/or function following an identified environmental insult (such as certain in utero or neonatal infections). An additional concern is that passing screening may reduce a family's vigilance with respect to late onset or progressive hearing loss, yet the likelihood of the latter increases in babies at very high risk of PHL, even if hearing were normal or near normal at the screening.

Babies bypass NHS if physically they cannot be screened, if their *a priori* likelihood of PHL is sufficiently large or if there are other factors such as pathogenic urgency. NHS bypass is mandatory for babies who have:

- bilateral congenital aural atresia
- confirmed meningitis, irrespective of the pathogen (viral, bacterial, fungal)
- cleft palate and unilateral atresia; they will receive stage 1 hearing screening and proceed to ABR audiometry after this regardless of the screening result

Babies who bypass NHS per the BCEHP NHS protocol receive a series of audiologic assessments beginning with ABR audiometry; the timing, frequency and duration of monitoring is dependent on the risk factor present. See Appendix ABR8 for recommended follow up schedules for children with a variety of risk factors.

MENINGITIS

In serologically confirmed meningitis, a common misconception is that only *bacterial* meningitis is a genuine risk indicator for PHL. However, this belief is not well-proven, and PHL has been shown for non-bacterial meningitis. Issues in meningitis risk include the time of onset of PHL and its progression. In bacterial meningitis, there is also risk of ossification of the cochlea that may compromise cochlear implantation. ABR audiometry must be done as soon as is medically possible following recovery from the acute phase of the illness, but in accordance with the timelines stated earlier (i.e., within 4-8 weeks corrected age). Detection of any sensorineural abnormality indicates urgent referral to an otolaryngologist and the BCCH Cochlear Implant program.

Likewise, if meningitis is suspected but confirmation is not accessible, screening should be bypassed and referral to ABR audiometry initiated. The conservative approach of routing to ABR audiometry has little downside, compared with the potential harm of missing an emergent PHL for several months. If a treating physician sees fit to refer the baby for ABR audiometry on the basis of presumptive meningitis, the baby is at risk due to the physician determination itself, and the ABR should be treated as though the meningitis was confirmed.

CONGENITAL STRUCTURAL DIFFERENCES

When there is an obvious, clearly recognizable anatomic anomaly of the external ear canal such as unilateral or bilateral congenital aural atresia or meatal stenosis, screening bypass is necessary because the probe tip cannot be inserted. Therefore, any baby who has a structural difference of one or both ears, such that an insert earphone cannot be placed for screening, should bypass screening when indicated as per the BCEHP NHS protocol and always be referred for ABR audiometry. ABR audiometry is always an assessment of *both* ears. In any atretic ear, the usual issues are the status of the cochlea and whether there is a functioning air-conduction pathway. Air-conduction testing by supra-aural earphones is required, given that ear canal patency is often difficult to determine by visual inspection. Follow-up with special programs for infants with congenital ear differences is recommended where such programs are accessible, such as at BCCH. Other management options are at the audiologist's discretion.

1.18 TIMELINESS OF ABR COMPLETION

> Incomplete ABR assessment after three appointments represents a significant quality-of-care challenge that compromises BCEHP's primary objective. Solutions to this challenge are a BCEHP CQI priority. PSA consultation must be considered in a timely manner. Prolonged deferral of assessment, such as deferring to visual reinforcement audiometry (VRA) several months later, must be avoided wherever possible.

Timely completion of ABR audiometry, as defined by international benchmarks for early hearing programs, is a priority for BCEHP. Two common measures of timeliness are (i) age at completion of ABR audiometry, and (ii) the time interval between referral to ABR audiometry and its completion. Age at completion is dependent on age at referral from newborn hearing screening and age at the first ABR audiometry appointment attended. Delay between referral and first appointment attended depends upon the efficiency of both referral generation and ABR audiometry appointment booking by audiology clinics, as well as parent engagement.

ABR audiometry appointment scheduling tactics such as reserved "emergency" appointments, pre-linked appointment pairs that allow rapid follow-up to complete unfinished ABR audiometry and age-driven appointment priority should be routinely practised by BCEHP audiology facilities offering ABR audiometry services. Excellent testing quality is of limited value if timely access is undermined by suboptimal appointment scheduling.

The duration of initial ABR audiometry, the time from the first appointment attended through to the point of ABR audiometry completion, may be delayed due to (i) inadequate test conditions and (ii) audiologic complexity. Obtaining little useful clinical information after attending several ABR assessments can result from inadequate test conditions. Common causes include: the baby being too old to sleep for durations required for ABR audiometry testing, developmental and/or behavioural factors, mismatch of appointment timing and sleep patterns, caregiver non-adherence to pre-test instructions, ineffective sleep induction techniques and inefficient testing strategy. The overriding imperative is that ineffective testing cannot simply be repeated indefinitely; issues stated above should be minimized before further testing.

Babies who fail newborn hearing screening bilaterally are especially compromised if testing is not timely. Babies with complex hearing loss, such as mixed hearing loss, asymmetric non-flat SNHL and/or ANSD usually require 2-3 test sessions. Efficient scheduling of appointments, careful attention to need for a sleepy baby and efficient ABR test strategies (as prescribed by this ABR audiometry protocol) are essential for babies with complex audiologic results.

If ABR audiometry is not completed after three attended sessions, the PSA must be consulted promptly. *Deferral to later VRA-based assessment is not an acceptable standard of care.*

In some cases where ABR audiometry is not yet fully complete after three attended sessions, the available ABR audiometry results may provide enough information to determine whether there is a need for prompt management and to define at least approximate amplification requirements, where amplification is indicated and elected.

1.19 REFERRAL FOLLOWING ABR AUDIOMETRY

For infants under 2 years of age (corrected), immediate referral will be made to BCEHP Service Coordination in all circumstances where the target disorder has been identified at the time of/shortly following ABR audiometry. Further, all infants for whom ABR audiometry indicates permanent hearing loss will be referred to the appropriate otolaryngology (ENT) practice for consideration of further testing and/or amplification before 6 months corrected age, unless otherwise contraindicated due to other health concerns.

For infants under 2 years of age (corrected) and identified with the target disorder, the ABR Audiologist will:

- make an immediate referral to BCEHP Intervention Service *Coordination* in all circumstances where the target disorder has been identified at the time of/shortly following ABR audiometry
- refer to the appropriate Otolaryngology (ENT) practice for etiology investigation, consideration of further testing and/or amplification before 6 months corrected age
- provide the appropriate ABR Results Card (on BERT) after the ABR assessment
- provide the Parent Resource Guide (infant version)

For children older than 2 years of age (corrected) and identified with PHL, the ABR Audiologist will:

- refer to the appropriate Otolaryngology (ENT) practice for etiology investigation, consideration of further testing and/or amplification
- support with next steps for intervention services (because they are not eligible for intervention *coordination* from BCEHP)
- provide Parent Resource Guide (child version)

1.20 CAREGIVER-DRIVEN SECOND OPINION

BCEHP does not support repetition of initial complete ABR unless it is elected by the primary ABR Audiologist and is determined to be appropriate by a PSA, in which case the process is considered as consultative referral.

In the situation where a second opinion request is driven by a caregiver, the ABR Audiologist can offer the option of PSA review as BCEHP's standard procedure. In consultation with the ABR Audiologist, the PSA will examine results and issue a written report on ABR inferences and recommendations. The recommendations may include re-testing locally or at BCCH.

Parents/caregivers always have the right to seek ABR audiometry services outside BCEHP; however, it must be explained to the parent/caregiver that, given the complex technical and procedural requirements for valid testing, the results of any such testing over which BCEHP has no jurisdiction may not qualify the child for BCEHP services.

1.21 ABR TESTING OUTSIDE BCEHP

Results of ABR testing done outside of BCEHP must be reviewed by a PSA for validity, accuracy and relevance, prior to provision of subsequent services funded by BCEHP. If the PSA considers that the outside ABR testing does not meet BCEHP's standard procedures, then ABR testing within BCEHP will be required.

1.22 INFECTION CONTROL STANDARDS

Infection control practices are typically governed by site-specific, institutional or agency protocols, and detailed review is outside the purview of this document. If local protocols are not available, generally accepted standards must be applied. The guidelines issued by the CSHBC are a possible source of further information.

Minimum infection control standards required by BCEHP are available in the BCEHP NHS protocol. The guidelines issued by the College of Speech and Hearing Health Professionals of BC (CSHBC) and BCCH are sources of further information. If there are discrepancies between the recommendations specified by BCEHP, CSHBC and site-specific requirements, the higher level disinfection/sterilization procedures should be used. Questions regarding local requirements should be directed to the Regional Coordinator.

CLEANING AND DISINFECTING EQUIPMENT (ROUTINE PRACTICES)

In brief, the reusable/shared medical equipment for ABR audiometry requires low-level disinfection because they are considered non-critical devices (i.e., they only touch intact skin and not mucous membranes). Non-critical devices that are visibly soiled must be cleaned first before a low-level disinfectant (e.g., CaviWipe Surface Disinfectant Wipes) is applied. This is because the disinfecting action of the solution can be hampered by the presence of dirt, organic matter, etc. The low-level disinfectant must be left to dry for the amount of time recommended by the manufacturer on the product label. If not visibly soiled, equipment and surfaces can be wiped using a single low-level disinfectant wipe at the start of the shift and between patients. Note that additional precautions are required if an infant is on isolation precautions (e.g., airborne, contact and droplet precautions).

1.23 APPROVED TEST ENVIRONMENTS

With the exception of medical/surgical facilities used for testing under sedation or general anesthesia, ABR audiometry must be conducted in an environment complying with current ANSI standards for maximum permissible ambient noise levels for audiometric test rooms [ANSI S3.1-1999 (R2018)].

Any environment that does not satisfy this ANSI standard (S3.1-1999) must be discussed with a PSA, approved by the CQI Panel, and be deemed satisfactory with respect to lighting, HVAC, visual distraction, transient and steady-state acoustic noise levels, electromagnetic artifact and audibility of brief-tone ABR stimuli at BCEHP mandatory minimum intensity levels.

Satisfactory test conditions for ABR audiometry may be achievable in a quiet, untreated room with little noise from people, traffic or HVAC systems. For alternative test environments to be considered acceptable by the BCEHP CQI Panel, measured octave-band Sound Pressure Levels must not exceed the following levels.

Octave band measurements:	
0.5 kHz	21 dB SPL
1 kHz	26 dB SPL
2 kHz	34 dB SPL
4 kHz	37 dB SPL

ADDITIONAL ROOM STANDARDS FOR ABR AUDIOMETRY

Electrical isolation is required (i.e., more than 8 m away from an elevator shaft; more than 8 m away from X-ray equipment and power doors). Facility management and clinicians must be aware of possible sources of electrical interference and be prepared to relocate the ABR audiometry room if other measures to isolate are not successful. A dedicated circuit is not a requirement. Access to a sink/hand sanitizer for hand washing within close proximity to the testing room is a requirement.

The optimal test environment for ABR audiometry is an audiometric soundroom that is electrically shielded. ABR audiometry test rooms should not be adjacent to strong sources of electromagnetic (EM) fields, such as heavy electrical equipment, elevators, HVAC motors, diathermy equipment, large scanners, etc. If a soundroom is shielded, then for optimal effectiveness against external fields, shield continuity (e.g., window mesh) and good grounding are important. Regardless of such shielding, main power cable routing within the soundroom must be appropriately encased in grounded metal conduit, and to the extent possible, outlets that are unused should have metal cover plates. Limiting the number of outlets installed within the test environment is also helpful to reduce potential EM noise.

HVAC is important, especially for infant comfort, sleep promotion and stable electrode-skin attachment (which is affected by sweating). Lighting control is important for sleep promotion; battery-powered LED task lighting is optimal with respect to power line interference. Fluorescent bulbs and tubes are the least desirable option, giving limited control of luminance, often creating ambient acoustic noise and having high likelihood of electromagnetic noise at 60 Hz and its higher harmonics (e.g., 120 Hz).

The current ABR equipment (Intelligent Hearing Systems (IHS), SmartEP module) is laptop-based, and noise levels from that unit are not a significant concern. Printing of records (laser or inkjet), if necessary, should be done offline, so it is not absolutely necessary to power up the printer during testing. Alternatively, the printer may be located outside the sound room, given adequate cable routing though the trap or connector panels.

ABR AUDIOMETRY ROOM FURNISHINGS

- a leather or otherwise easy-to-clean (wipeable) recliner in which a parent can hold a sleeping infant for one to two hours
- alternate sleeping arrangement for baby (e.g. crib or bassinet)
- a pillow in a plastic case with linens to allow greater comfort for parents when holding their infant
- ABR equipment on a moveable cart/computer desk
- a comfortable chair with wheels, for ABR Audiologist
- additional chair for second parent or other support person
- side table for water and tissue box

OTHER REQUIRED EQUIPMENT (USUALLY WITHIN THE SAME ROOM OR WITHIN CLOSE PROXIMITY)

- otoacoustic emissions equipment
- acoustic immittance equipment with high-frequency tympanometry and acoustic reflexes

1.24 APPROVED TEST INSTRUMENTATION

All instrumentation used for ABR audiometry must be approved by BCEHP. ABR testing must be done using the Intelligent Hearing Systems SmartEP with appropriate EP software setup and hardware. Ancillary equipment for otoacoustic emissions, tympanometry, acoustic reflex testing and RECD measurement must satisfy the functional specifications detailed in Section 6 and must be approved by BCEHP.

BCEHP provides the instrumentation necessary to conduct ABR audiometry assessments according to this protocol. The IHS SmartEP system is provided with appropriate SEPWIN software setup and hardware, transducers and protocol setup files.

For DPOAE assessment, most pediatric audiology clinics in British Columbia currently use the Natus Bio-logic Scout system, Interacoustics Titan/Lyra , GSI Corti or Otodynamic ILO Clinical OAE systems. Other systems may be used for DPOAE testing given they satisfy the specifications detailed in Section 6.1.

Tympanometry and acoustic reflex testing is most frequently conducted using the GSI Tympstar but may be completed on any equipment capable of providing the measures and procedures specified in Sections 6.2 and 6.3.

1.25 APPROVED DEVICE PROTOCOLS AND PARAMETERS

All device protocols and parameters must be configured exactly as specified in relevant sections (see Appendix ABR3 for ABR parameters/setup details and Section 6 for DPOAE and Tympanometry specifications). Departure from specified parameters may compromise test validity or efficiency and will be considered to be out-of-protocol. Setup for new equipment may be arranged with the local device supplier approved by BCEHP.

1.26 DOCUMENTATION AND CLINICAL RECORDS

Clinical records must include all the information listed below. This includes the following printed/electronic materials: ABR waveforms, ABR recording sheet, tympanometry results (if done), DPOAE results (if done), AR results (if done). The clinical report for the ABR assessment must include a table of the ABR thresholds in dB eHL, and either the corresponding Normal Hearing Level (nHL) or Estimated Behavioural Hearing Level (eHL) correction factor. All results must be entered in the BEST data system.

The data and documentation procedures described below are mandatory. They will be examined for completion as part of the routine document-based practice review by the CQI Panel, as well as in any Adverse Event Reviews. Additional, non-BCEHP, site-specific processes and requirements may also be in place.

DOCUMENTATION IN THE PATIENT/CLIENT CHART

The following items are required:

- ABR waveforms printouts/PDF, displayed using the recommendations outlined in Section 3.2.
- ABR recording sheet(s), including file names, stimulus parameters, response judgments for groups of replications (i.e., RP, NR, CNE), relevant patient/test environment issues, rationale for departures from protocol.
- acoustic immittance printouts/PDF (if acoustic immittance measures obtained)
- OAE printouts/PDF (if otoacoustic emission measures obtained)
- audiogram (if behavioural measures obtained)
- clinical report, signed by the testing ABR Audiologist and with printed name, regardless of whether any external report is being issued. The clinical report for the ABR assessment must include: (i) a table of the ABR results in dB eHL and either the corresponding nHL or eHL correction factor and (ii) the date, test(s) performed, final result for that assessment and recommendations made.

For any test performed where printouts/PDF are not on file, documentation of the reason that they are not present is required.

BC EARLY HEARING SURVEILLANCE TOOL (BEST)

BCEHP oversees a provincial data system called the BC Early Hearing Surveillance Tool (BEST), which includes early hearing and intervention data from all of the regional health authorities and intervention service agencies. Each region or agency is responsible to input their own clinical data into BEST in order to receive services through BCEHP.

For each assessment, results of the assessment (even if incomplete) must be entered in the BEST data system as a single assessment. Results should be entered as completely as possible as allowed by the format of the BEST data system (e.g., frequency-specific and test-specific data entry). **For ABR audiometry that occurs over more than one test session, results must be entered in BEST in a cumulative way**. This will ensure that the final ABR entry for any given child represents "all" the data obtained. This facilitates review by colleagues as well as BCEHP Provincial Office for amplification funding approvals. When results are combined from multiple test sessions, a comment indicating session dates is important to include. **BCEHP requires that all assessments (e.g., ABR, behavioural, OAEs, tympanograms) for a child be entered up until age 5 years.**

REPORTING

In addition to the BEST entry, there must be a formal clinical report in the patient/client chart, signed by the ABR Audiologist and with a printed name, regardless of whether any external reporting is issued. Clinical ABR audiometry reports must include numerical ABR results in dB eHL, as well as a prose summary and interpretation of the results. In addition to providing dB eHL results in the ABR table of the clinical report, current correction factors (dB nHL to dB eHL) to determine dB eHL (dB estimated hearing level) results must be included. By providing these two numerical values, external users can easily determine dB nHL levels.

Below is an example ABR table to be placed in a report

Below is a summary of Auditory Brainstem Response (ABR) results		
Frequency (kHz)	Estimated Behavioural Threshold (dB eHL)	
	LEFT EAR	RIGHT EAR
AC 0.5	≤25	≤25
AC 1	≤25	≤25
AC 2	≤25	≤25
AC 4	≤25	≤25

(AC=air conduction; BC=bone conduction; eHL=estimated behavioural threshold in dB HL; nHL-to eHL conversion: AC: -10, -10, -5 and 0 dB for 0.5, 1, 2 and 4 kHz respectively; BC: +5 for 0.5 and -5 dB for 2 & 4 kHz; BCEHP normal limits are ≤25 dB eHL)

CONSENT FOR RELEASE OF INFORMATION

A report sent externally (i.e., outside of BCEHP and the ABR centre) is highly recommended for all assessments. For reports sent externally, consent for release of information should be signed by the child's parent or guardian and should be documented in the patient/client chart. Site-specific procedures and documents will be in place and should be followed.

CONSENT FOR SERVICES

The College requires that consent for services be obtained prior to any child receiving audiological services. Site-specific procedures and documents must be in place and should be followed.

ARCHIVING/BACK-UP OF ELECTRONIC DATA

Electronic data, such as those generated by OAE and ABR testing, should be regularly backed up to the facility's secure network server. This backup procedure should be carried out at least every 6 months. See Appendix ABR2 for instructions on how to use IHS's backup utility.

1.27 PERSONAL HEALTH INFORMATION

Requirements of the British Columbia's *Freedom of Information and Protection of Privacy Act* must be met.

ABR data files stored on laptops and removable media must not be identifiable. Data communicated for approved monitoring and review procedures must be de-identified and code-referenced using the unique 10-digit "BCEHP number" generated by the BEST database. Individual case information transmitted by fax, hardcopy or email, such as for BCEHP training follow-up, PSA clinical decision support, CQI Standard Practice Reviews or Adverse Event Reviews must be uniquely code-indexed using the BCEHP number and thereby rendered personally non-identifiable to unauthorized third parties.

2 ABR AUDIOMETRY PRELIMINARIES

2.1 URGENCY OF ABR APPOINTMENTS

Timely attendance for ABR audiometry is critical for achievement of international benchmarks for ABR completion. Initial ABR appointment scheduling is also affected by timeliness of screening, appropriateness of messaging to caregivers at screening referral and the effectiveness of ABR appointment scheduling.

Once a baby has failed newborn hearing screening or has been routed to bypass screening, the need for timeliness of ABR audiometry from its initiation to its completion cannot be overemphasized. First, caregiver anxiety accumulates over time. Second, in order to meet international performance benchmarks and gain the greatest benefit from newborn hearing screening, the initial ABR audiometry process must be completed by 3 months corrected age. This requires an early ABR audiometry start, to allow for additional test sessions that are necessary for many babies who have hearing loss and to accommodate inevitable delays due to unforeseen events such as baby indisposition or competing caregiver demands. Third, as babies get older, natural sleep becomes increasingly challenging to initiate and maintain for the required length of testing. This can lead to incomplete ABR audiometry, reduced test accuracy, inconclusive results and increased program resource consumption, including possible need for testing under sedation. Nevertheless, a delay of a few weeks between newborn hearing screening referral and the first ABR audiometry appointment is indicated in order to facilitate resolution of transient, perinatal ear conditions, ease of handling the baby and some undisturbed caregiver acclimatization to their new circumstance and daily routines.

It is essential that the caregiver understands the purpose and importance of prompt assessment. This begins with the hearing screener giving appropriate and timely explanation and messaging, which should be reinforced at every opportunity through the ABR audiometry appointment booking process. Families must be made aware of the importance of securing the earliest available appointment, the reasons for the pressure of time and the possible consequences of delay, especially the necessity of sleep and its increasing difficulty over time. The key message is that the sooner the test is done, the quicker and easier it is likely to be. Families also should be made aware that ABR audiometry appointments are a scarce resource for which many other families are waiting, so (i) they should make every effort to keep the appointment and (ii) if they become aware of inability to attend, they should immediately notify the ABR test clinic and rebook as soon as possible.

Factors that are reported to facilitate prompt appointments and high attendance rates include:

- appointment slot filling taking into account the 4-8 week target dates (i.e., not filling all available slots simply on a first-come, first served basis)
- maintaining reserved (non-routine, protected) slots for unexpected and/or high-priority/urgent appointments
- automatic allocation of prompt, linked follow-up slots for rapid ABR audiometry completion in a proportion of primary slots (such as one in five, depending on referral population characteristics)
- reinforcing key messages at every booking/reminder contact, both in writing and verbally
- maintaining a short-notice waiting list to fill late-notified non-attendance
- routine 2-week and 2-day appointment reminders and confirmation requests

In situations of irremediable limitation of access to timely ABR appointments, ABR appointment filling should be done in such a way as to maximize program benefit within existing resource constraints. It is important to minimize the occurrence of late access to ABR for babies who have the highest likelihood

of having PHL, such as those who bypass hearing screening, who are at high initial risk of PHL or who fail hearing screening bilaterally. Scheduling of ABR testing for low-likelihood babies should not saturate available appointments in such a way as to cause late access for babies with a high likelihood of PHL.

2.2 PRE-TEST BABY STATE

Accurate ABR audiometry is possible only in natural sleep, sedated sleep or under general anesthesia. Natural sleep is the first choice for young infants under 6 months corrected age and must be tried initially except for exceptional circumstances (e.g., long-distance travel or prior failure to sleep). The baby should arrive for ABR hungry and tired but not asleep (nor having slept in the few hours before the appointment). Variable adherence to pre-test instructions can be a barrier to timely completion of ABR audiometry.

Natural sleep is readily achieved in most babies under about 3 months of age but becomes progressively more challenging thereafter. Appropriate training, test protocols and infant management methods are necessary and sufficient. Appropriate and effective instruction to families about pre-test preparation is crucial.

Successful induction of natural sleep in a wide range of babies is an adaptive skill that takes time and experience to acquire. The infant should arrive for the appointment hungry and tired, though not overtired. It is normally appropriate to deny sleep and food for at least an hour before testing, where not medically contraindicated. If the child is being brought to the test by car, it is important that every reasonable effort be made (consistent with safety) to keep the child awake on the journey. Because car journeys often make infants sleepy, another person in addition to the driver is usually necessary. The potential futility of attempting assessment in a poorly prepared infant is stressed. After cursory otoscopy and ABR electrode attachment, the baby can be fed and prepared for sleep.

ABR testing facilities in British Columbia utilize testing schedules with targeted appointment start and stop times. A typical duration for a routine ABR appointment is 2.5-3 hours. In that time, it is usually desirable that the baby sleep for at least half an hour, during which a baby without PHL normally can be confirmed as such, when efficient ABR protocols are followed. For babies with hearing loss, especially those with more complex hearing loss, this time is enough to confirm the presence and type of hearing loss; however, often a second ABR audiometry test session, and occasionally a third session, is required to completely characterize the hearing loss (Hatton et al., 2019; Janssen et al., 2010).

2.3 ABR INSTRUCTIONS FOR PARENTS/CAREGIVERS

Effective processes that involve clear messaging about the effects of pre-test sleep and subsequent test failure are essential for maximizing the likelihood of ABR success. The real underlying message to the family is that if the baby does not fall into a deep sleep for at least half an hour, the session is unlikely to be useful.

The infant's behavioural state upon arrival for assessment is important for successful testing in natural sleep. Parents are encouraged to make every reasonable effort to ensure that the infant arrives for testing in an appropriate state. It is essential that families understand very clearly that successful ABR testing depends on their following pre-test instructions carefully, and they should be given detailed instructions on what and what not to do. Effective processes that involve clear messaging about the effects of pre-test sleep and subsequent test failure are essential for maximizing the likelihood of ABR success. The real underlying

message to the family is that if the baby does not fall into a deep sleep for at least half an hour, the session is unlikely to be useful. In a group practice or institutional situation in which staff members who make family contacts for appointments may vary in their engagement and communication skills, scripts or other supports may be helpful to encourage strong and appropriate messaging.

The degree to which families follow pre-test instructions varies across ABR test facilities in British Columbia. Multiple factors are involved, and some of those factors are within the scope of influence of the ABR Audiologist. The best that reasonably can be done is that families hear and fully understand the message, then make an honest effort to comply with the instructions. The bare minimum process requirement to achieve this is that the messages are very simple, brief, clear, strongly directive and consistent. Written instructions and telephone confirmation are recommended.

See BERT for ABR Test Instructions.

2.4 SEDATED ABR

> Routinely resorting to sedation or general anaesthesia in infants under 6 months corrected age is not recommended and, fortunately, is largely unnecessary given adequate preparation for natural sleep induction by parents and clinicians. Testing under sedation requires physician referral and medical or nursing supervision of the infant during the testing.

Although there is wide variation in practices for sedation, BCEHP strongly recommends a conservative standard of care. Routinely resorting to sedation or general anaesthesia in infants under 6 months corrected age is not recommended and, fortunately, is largely unnecessary given adequate preparation for natural sleep induction by parents and clinicians. Testing under sedation requires physician referral and must be done under medical order and with medical or nursing supervision of the infant from the time of administration through to the end of the indicated recovery period. Immediate access to respiratory support and emergency services is appropriate, but local safety protocols are the determining factor of what is required in a given test setting.

Testing under sedation may be necessary in infants for whom acceptable behaviour and EEG conditions cannot otherwise be obtained. Usually, at least one attempt to test in natural sleep would have failed before resorting to sedation. It is reasonable to consider fairly routine use of sedation in children older than 5-6 months or for children who have to travel long distances for assessment, because it is especially important to have a reasonable assurance of success. BCCH routinely uses sedation in infants older than 6 months of age.

The audiologist determines that sedation is indicated on audiometric grounds, whereas the family, in consultation with the audiologist and appropriate physicians and nurses, determines whether sedation will actually occur. The infant's pediatrician, family physician or otolaryngologist must be involved, as he or she may have unique knowledge of contraindications or risk indicators in the client's history. If sedation is indicated and the parent consents, a physician should prescribe the sedative agent (usually oral chloral hydrate and/or nasal dexmedetomidine). Appropriate risk management procedures to guard against rare adverse events such as respiratory depression should be in place. Because not all ABR Audiologists will have access to sedation, cross-referral to another ABR Audiologist who has a sedation practice may occur.

In a few infants, especially those with neurological and/or behavioural disorders, the response to sedation may be paradoxical activation. This has been addressed in various ways: by increasing the dosage of the sedative, by using alternative medications or by resorting to light, general anaesthesia. The indications for these procedures are a matter for local risk management protocols and standards of care.

Testing under general anesthesia is sometimes undertaken where medically appropriate and opportune. In the operating room, problems with electrical interference (especially 60-Hz) is common, and special adjustments to recording parameters may be required.

2.5 TEST ROOM AND PARTICIPANTS

Test areas should be as conducive as possible for baby sleep and caregiver comfort. Important factors are low sound levels, adequate heating, ventilation and air conditioning, low lighting, good electrical shielding, negligible in-room 60-Hz electrical interference and effective positioning of the equipment and all persons present. For ABR testing in natural sleep, caregiver presence may be preferred, and their assistance is often effective, given appropriate instruction.

The infant's safety and comfort are paramount, and the infant must be monitored continuously. Normally, the ABR Audiologist and instrumentation are inside the sound room, with the infant, who may be held by a parent/caregiver, or in a bassinet, crib or car seat/stroller.

In most test situations, it is feasible for a single ABR Audiologist with appropriate training to conduct ABR testing. Extra assistance is sometimes required – for example, in some cases, hand-holding the BC transducer may be difficult without assistance – and additional trained personnel such as a nurse, audiometric technician, second audiologist or other assistant may be called in.

Attendance of family members/caregivers during ABR testing is common but is a matter of local clinic preference and at the discretion of the ABR Audiologist. In specific situations, the presence of a family member or third party may be desirable for reasons unrelated to test quality, such as to secure compliance or to manage perceived medico-legal risk. Family members may differ in their knowledge and skills related to infants' sleeping habits.

Having parent(s) in the test room, at least initially, can alleviate their anxiety. They can assist by trying to get their child to sleep. Caregiver engagement with the ABR audiometry process can contribute substantially to understanding of test results, the building of trust and the creation of a communicative relationship with the ABR Audiologist that may prove crucial in subsequent management, should the baby be proven to have PHL.

If a caregiver is present during the testing, it is important that the ABR Audiologist pay special attention to appropriate communication of information as the test proceeds. Surveys of caregiver experience with ABR audiometry assessments indicate that caregiver satisfaction is often less than ideal, most frequently as a result of not being kept at least minimally informed about what is going on. It is often helpful to let the family know at the start of the appointment that test results will be communicated to them at the end of the assessment and that discussion during the test session will be minimal to take full advantage of baby's sleep time in order to get the most information possible.

For example, the ABR Audiologist might say: "I need to focus on the testing and my equipment while your baby is sleeping, but at the end of the testing, I will let you know everything I've learned."

A running commentary by the ABR Audiologist is neither appropriate nor practical given the technical demands of ABR, but reasonably frequent, brief explanations of what is being done can alleviate the caregiver's sense of being "kept in the dark" and lacking control. Discretion and good judgment in communication are essential if the ABR Audiologist is facing what appears to be a baby with major PHL.

2.6 ORDER OF TESTS DURING ABR APPOINTMENT

After cursory otoscopy, ABR audiometry is usually the first procedure, followed by tympanometry and DPOAE (when required).

Cursory otoscopic examination at the start of the assessment is mandatory. Its main purpose is to detect foreign bodies, canal occlusion and any physical condition of the ear that indicates referral to a physician under standard red flags. Otoscopy is usually followed by skin preparation, electrode attachment, then feeding to promote sleep.

At the initial ABR audiometry session, tone ABR is the immediate priority as soon as the infant sleeps. If not obtained prior to sleep, other procedures such as tympanometry and DPOAE testing are usually deferred to the end of the first ABR audiometry session. A general principle is that one should first obtain results that provide the most important information.

There are a number of arguments that favour starting with ABR audiometry right after otoscopy:

- ABR is the core procedure, and because doing other tests (tympanometry; DPOAEs) up front may irritate the child or consume valuable sleep time, ABR success may be compromised. This may be a more significant issue for older infants or those who are inherently irritable or disinclined to sleep.
- DPOAE and tympanometry tests do not provide threshold information but can provide important supplemental information about the status of cochlear outer hair cells and the middle ear, respectively. DPOAEs are easily obscured by even minor conductive pathologies. For example, a flat tympanogram and/or absent DPOAE cannot indicate the presence of a clinically significant hearing loss, as both may occur with only a 5-dB conductive loss. In contrast, an absent ABR at 30 dB nHL indicates a threshold elevation. Only when tympanometry or DPOAE results are present and normal do they provide information.
- Because abnormal AC tone-ABR thresholds trigger BC-ABR measurements, direct evidence of CHL is usually obtained. Tympanometry is usually deferred at least to the end of the first session. Its findings complement ABR-based inferences and provide some but limited cross-validation of ABR air-bone gaps.

After the tone thresholds are substantially completed, if the 2-kHz ABRs are absent or abnormal at high levels, then ANSD presence must be evaluated, using both DPOAEs and the click-ABR ANSD protocol. These tests are normally deferred to the end of the first ABR audiometry session or at the start of the second session.

Following completed ABR audiometry, in a small proportion of cases, more advanced procedures, such as threshold estimation with cortical auditory evoked potentials (CAEPs), or more complex ANSD testing to disentangle receptor and neural potentials may be indicated under specific circumstances, such as inability to measure hearing thresholds by ABR or VRA, or inability to interpret results of the standard ANSD protocol (see Section 5). The need for such procedures is identified by a PSA consult, and these advanced procedures would normally be done at BCCH.

3 TECHNICAL ASPECTS OF ABR AUDIOMETRY

3.1 TONE STIMULUS PARAMETERS

BCEHP tonepip parameters of 2-1-2 cycle linear rise/plateau/fall modulation (or 5-cycle exact Blackman), calibrated using BCEHP standards, must be used. The accuracy of ABR thresholds and derived behavioural threshold estimates are specific to these stimulus parameters and to the other parameters and procedures specified in this ABR protocol.

ABR audiometry must be done using the IHS SmartEP system, as provided by BCEHP. All application test protocols and parameter files must be configured exactly to BCEHP specifications (see Appendix ABR3: Technical Details).

The core of ABR audiometry is the estimation of hearing thresholds using tone-ABR methods. The accuracy of the threshold estimates obtained depends upon many details of the stimulation and recording methods specified in this protocol. The estimation process involved analysis of normative data on the relationship between tone-ABR thresholds and subsequent behavioural thresholds obtained by VRA that have been presented in many studies, including those obtained by Stapells and colleagues (Stapells et al., 1995) and more recent research (for comprehensive review of these studies, see: Small & Stapells, 2017). The results of this estimation process underlie the adjustment factors ("eHL correction factors") that are used to convert tone-ABR thresholds in dB nHL to estimates of perceptual thresholds in dB HL.

The eHL correction factors used in this protocol *are specific to the stimulus parameters, recording and analysis techniques described in this document.* Use of any other types of stimuli, including "chirp" stimuli, changes in nominal tone frequency or changes in any of several specific aspects of ABR recording and analysis (such as averaging strategy or residual noise criteria) will render the threshold estimation process invalid and of unknown bias and precision. Conversely, the correction factors used here cannot be assumed to be valid for stimulation and recording methods that differ from those specified in this protocol.

This protocol specifies the use of constant correction factor values for an ABR-threshold range of 15-25 to about 100 dB nHL. These eHL correction factors do not apply to AC-ABR thresholds less than 15-25 dB nHL (predictive strength of AC-ABR thresholds < 25 dB nHL using similar methods is not well established).

Some reports suggest a tendency for differences between ABR and VRA thresholds to decrease in individuals with more severe hearing loss. However, the effect, if real, is small in terms of estimated behavioural threshold accuracy and may be due to procedural issues (see Small & Stapells, 2017 for further explanation).

It should be noted that BCEHP tone stimuli are specified to have trapezoidal envelopes with linear rise and fall; the rise, plateau and fall times are 2-1-2 cycles of the stimulus frequency. Alternatively, 5-cycle duration exact-Blackman windowed tones may be used. Several studies have shown no difference in the frequency specificity between these two types of stimuli (Oates & Stapells, 1997a, 1997b; Purdy & Abbas, 2002). Recently, some researchers have suggested stimuli such as "narrowband chirps" *may* be more optimal or, perhaps, more efficient for ABR audiometry (e.g., Cobb & Stuart, 2016; Ferm & Lightfoot, 2015; Ferm et al., 2013; Rodrigues et al., 2013; Sininger et al., 2018). However, there are downsides to these new stimuli. Narrowband chirps have poorer acoustic frequency specificity than 2-1-2 tones (Adjekum et al., 2019) and thus may result in poorer estimates of frequency-specific hearing thresholds (currently under investigation). Also, narrowband chirp stimuli currently offered in clinical systems may or may not result in larger response amplitudes at higher stimulus levels, depending on the design of the chirp stimulus. Importantly, relatively few data with air- (AC) and bone-(BC) conducted narrowband chirp stimuli are available in the literature,

especially in large studies of infants and young children with hearing loss, to justify using them for ABR testing frequency-specific hearing thresholds. Currently only the linear 2-1-2 or exact-Blackman tone stimuli have the required substantive and high-quality normative data (in infants and young children), as well as wealth of clinical and research experience. Thus, *the ABR audiometry protocol utilizes only tone stimuli with either linear 2-1-2 cycles or exact-Blackman 5-cycles.* BCEHP will continue to evaluate research considering new stimuli and other new procedures, some of which is currently being carried out at UBC.

3.2 STIMULUS CALIBRATION AND CHECKING

BCEHP calibration values must be used, not the manufacturer's default values; annual electroacoustic checks, daily listening checks and, if non-response unexpectedly occurs at high levels, stimulus verification must also be conducted. Poor plug/socket contact or defective leads are common causes of stimulus failure or intermittency. On-site backup calibrated transducers and leads should be available at each site.

Annual acoustical calibration of the IHS SmartEP system stimuli and masking noise is a formal BCEHP requirement. All BCEHP tests will be done using current BCEHP calibration and setup files and maintained according to BCEHP specifications. The *manufacturer's factory-supplied setup and calibration details for the IHS SmartEP system are NOT acceptable* for BCEHP assessments because the experimental and psychophysical basis for the calibration specifications are usually not available for evaluation, nor are they independently validated. The calibrations used by BCEHP are based on the published findings of Stapells and his co-authors (for review, see Small & Stapells, 2017) and are detailed in Appendix ABR3 and ABR4. BCEHP is responsible for the determination and dissemination of reference settings for the calibration files that govern stimulus levels for ABR testing. Correct system setup files and acoustic calibrations will be provided by BCEHP. The calibration data will be updated from time to time, as further information becomes available from published research or BCEHP clinical practice.[3]

BCEHP ABR systems are calibrated by BCEHP-designated acoustic calibration technicians familiar with BCEHP's specifications for calibration of stimuli for electrophysiologic measures. All transducers (ER-3A insert earphones; TDH supra-aural earphones; B-71 & B-81 bone oscillators) must be calibrated using a sound-level meter, and transducer output waveforms must be visualized (preferably recorded) using an oscilloscope (or other equipment) to evaluate transducer quality. Poor transducer quality (due to aging) might greatly distort stimulus outputs (e.g., ringing) that can generate stimulus distortions and large electrical stimulus artifacts within the ABR recording interval. This can lead to challenges with differentiating stimulus artifacts from physiological signals (e.g., cochlear microphonic). Clamped-tube runs will often demonstrate this prolonged artifact ("ringing"). Thus, large ringing stimulus artifacts can render ABR recordings uninterpretable. If transducers have large stimulus ringing artifacts within the ABR recording interval (0 to 25.6 ms), they should be replaced.

Because transducer malfunction can occur at any time, additional listening checks for transducer malfunction should be done just prior to testing and if/when non-response unexpectedly occurs at high levels. The most common cause of stimulus insufficiency is blockage of the foam eartip. Poor plug/socket contact or defective leads are also common causes of stimulus failure or intermittency. *The individual ABR Audiologist is responsible for these routine listening checks.*

[3] BCEHP does not use the Reference Equivalent Threshold Sound Pressure Levels (RETSPLs) proposed by Fedtke and Richter (2007). No force levels for bone conduction (RETFLs) are provided, and there are few published data for infants with hearing loss using these RETSPLs. Additionally, there are technical concerns with these RETSPLs and their calibration (Burkard, 2012)

It must be noted that busy clinics conducting several (4-5) ABR assessments each week will likely have to replace their AC and BC transducers every 2-3 years (and earlier if indicated by listening checks or annual calibration). On-site backup calibrated transducers and leads should be available at each site. See Appendix ABR3 concerning stimulus specifications and Appendix ABR4 for acoustic calibration.

3.3 STIMULUS TRANSDUCERS

BCEHP-approved air conduction (AC) (insert and supra-aural) and bone conduction (BC) (either B-71 or B-81) transducers are required. Insert earphones must be used for AC testing unless contraindicated anatomically. BC transducers will normally be hand-held by the audiologist or a trained assistant. The BC transducer must not be held by an untrained individual.

All stimulus transducers must be of the type specified by BCEHP. ABR measurements by AC will be done using insert earphones, except where specifically contraindicated anatomically (e.g., ear-canal atresia), in which case supra-aural earphones (TDH/MX41) will be used. ABR measures by bone conduction (BC) will be done using a B-71 or B-81 bone transducer. All BCEHP ABR sites will be equipped with calibrated insert and supra-aural earphones and either a B-71 or B-81 BC transducer.

AIR-CONDUCTION TRANSDUCERS

For AC testing, pediatric-sized foam eartips are preferred over supra-aural headphones as they have several advantages, including: reduced stimulus artifact, decreased background noise, less acoustic cross-over, decreased likelihood of collapsed canals and increased comfort. Often the foam tips must be cut down in thickness (not in length) for a very young infant.

Supra-aural earphones (TDH/MX type) are bulkier, more restrictive in terms of infant position and require more skill and attention to maintain proper placement than insert earphones. Typically, supra-aural earphones are handheld on each ear. Conducting the test and applying a supra-aural earphone without assistance may be difficult for the ABR Audiologist, whereas a single tester can usually implement the test with insert earphones.

Supra-aural earphones must be used when insert phones are contraindicated, such as when the ear canals are very small or highly stenotic or when the infant does not tolerate a foam eartip. Careful attention to accurate, axial placement of a TDH earphone and avoidance of canal collapse by excessive pressure, are especially important to ensure appropriate stimulus levels.

BONE-CONDUCTION TRANSDUCERS

BC-ABR testing will be done with careful placement of the BC transducer supero-posterior to the canal opening of the individual test ear. To achieve proper application force (at least 400 grams) and stable retention, the BC transducer will be secured firmly in place by hand by an individual specifically trained in this procedure. BCEHP recommends that the transducer be held by the audiologist or a trained assistant. Provided the audiologist is seated comfortably next to the infant being tested, the audiologist performing the assessment can often hold the transducer on the head while testing. The transducer must not be held by an untrained individual. Responsibility for appropriate application of

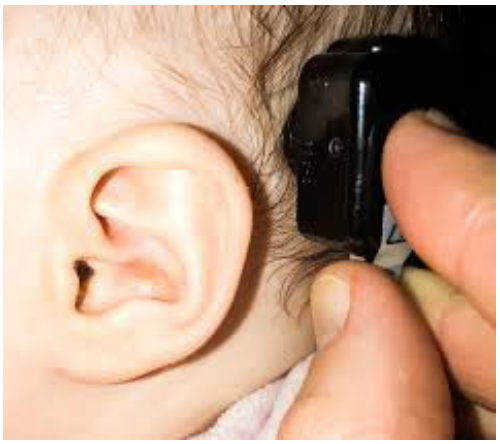


Figure 3.3.1: Placement of bone transducer.

the BC transducer lies with the testing ABR Audiologist. If BC-ABR results are abnormal, the ABR Audiologist must ensure it is not due to incorrect BC technique (i.e., incorrect positioning, insufficient force application).

See Appendix ABR5 for BC Hand-held Transducer Instructions.

Research at UBC (Small et al., 2007), as well as clinical experience, has demonstrated that the hand-held method, under controlled conditions, allows quick and effective BC-ABR testing. Moreover, experience has shown that this method is less likely to awaken the infant compared to use of an elastic band. This is because removing and switching the BC transducer position under the elastic band can more easily disturb a sleeping infant compared to simply placing the BC transducer on the test mastoid when holding it by hand. Application force measurements are not required after the individual holding the BC transducer has been trained to exert the required amount of force. Note that the metal bone-conductor band used in behavioural testing should not be used for BC-ABR testing as it is uncomfortable, easily slips off during testing and does not provide sufficient or calibrated application force for young infants.

Insert earphones do not need to be removed for BC-ABR testing in infants aged 12 months or less. The occlusion effect results when earphones are in place during BC testing. Skull vibration produces relative motion of surrounding air molecules which deforms the ear canal wall (mostly the cartilaginous part) and generates sound pressure that can be transmitted to the cochlea. The increase in AC sound pressure is greatest at ≤ 1 kHz in adults. Unlike adults, the occlusion effect is negligible across frequencies in infants aged 12 months or less, as indicated by research at UBC (Small et al., 2007; Small & Hu, 2011), such that insert earphones do not need to be removed for BC-ABR testing. For older infants (> 12 mos), there is a small occlusion effect (5-8 dB) at 0.5 and 1 kHz; thus, to be conservative, insert earphones should be removed from both ears (unless contralateral masking is being employed) when testing these frequencies in older infants (Small & Hu, 2011).

3.4 ELECTRODE POSITION

Four electrodes are required. The non-inverting ("+") electrode must be on the forehead midline, as high and as close as possible to the hairline. The inverting ("-") electrodes must be on each mastoid (as low as possible but not on the neck), and the common/ground electrode must be on the forehead, with at least 3 cm between the common/ground electrode and non-inverting electrode.

ABR electrodes must be of a type approved by BCEHP. Use of four recording electrodes is required by BCEHP for ABR recordings:

- non-inverting ("+") electrode must be in the forehead midline, *as high and as close as possible to the hairline*
- inverting ("-") electrodes must be on each mastoid, *as low as possible* (but not on the neck)
- common/ground electrode must be on the forehead, with at least 3 cm between the common/ground electrode and non-inverting electrode

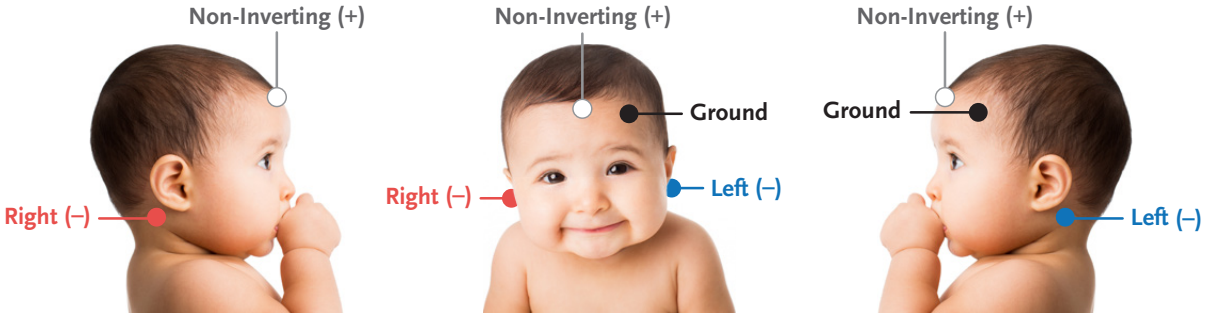


Figure 3.4.1: Electrode placement.

The use of four electrodes allows two differential recording channels: forehead-to-left mastoid and forehead-to-right mastoid. A common error is placement of the non-inverting electrode too low on the midline forehead, at which point ABR wave V amplitude loss will occur, relative to points higher on the midline. (On the International EEG Federation's 10-20 System for Electrode Placement, the goal is to position the non-inverting electrode as close as possible to Fz, *not* at the mid-forehead frontal pole denoted as Fpz.) Using sticky pads on the skin, the anterior proximity to Fz is usually limited by the position of the hairline. Thus, a compromise is to place the non-inverting electrode as close as possible to the hairline, which is typically closer to the Fz than Fpz location. Inverting electrodes are placed on each mastoid area as low as possible on the mastoid bone. This is done to reduce/remove contamination by the post-auricular muscle response (PAMR) and to be sufficiently far away from the BC transducer placement that is placed higher on the mastoid to help limit BC stimulus artifact. The common electrode is placed elsewhere on the forehead (e.g., lateral forehead), not within about 3 cm of the non-inverting electrode.

Site preparation using a mild abrasive is recommended; however, excessive abrasion must be avoided. Electrode wires should be led away from where the transducers (air or bone, but especially bone) are to be placed; electrode wires should be kept close together, short and preferably braided to decrease 60-Hz artifact. To reduce size of any stimulus artifact, electrode wires should be placed as far away as possible from AC and BC transducers and their wires; do not cross electrode and transducer wires.

Use of a midline neck (C7 spinal) position for the inverting electrode is NOT appropriate. Although a C7 electrode may yield slightly larger ABR wave V amplitudes, this position is problematic because (i) there is increased EM noise which offsets any increased wave V amplitude, (ii) ipsilateral/contralateral waveform cues used to assess stimulus laterality that are crucial for interpreting BC ABR are not available and (iii) because C7 is far away from the cochlea and cranial nerve eight (CN VIII), recordings of ABR wave I (CN VIII) and the cochlear microphonic (cochlea) will be lost; these results are needed when conducting click-ABR assessments.

3.5 ELECTRODE IMPEDANCES

Low electrode impedances (target under 3 kΩ) and small differences in impedance between electrode pairs (target under 1 kΩ) should be a priority. Electrode impedances must be noted during patient setup. Attempts to minimize electrode impedances (target under 3 kΩ) should be performed in order to reduce the effects of high electrode impedances on the ABR recordings.

Low electrode impedances (target under 3 kΩ) and small differences in impedance between electrode pairs (target under 1 kΩ) must be a priority.

Electrode impedances can have significant effects on EEG quality and, therefore, on successful ABR testing. Electrode impedance does not affect the ABR itself, but the larger the impedance (or impedance differences between electrodes), the larger the amount of pickup of external electromagnetic interference and of artifacts from movement of the electrode leads. Every reasonable effort should be made to obtain impedances of less than 3 kΩ for all electrodes. Even more important is the symmetry of the impedances within each differential pair. These must be as similar as is possible with reasonable effort. A maximum difference of 1 kΩ between inverting and non-inverting electrodes is a target. For example, if the right mastoid inverting electrode has an impedance of 3 kΩ and the forehead non-inverting electrode has an impedance of 1 kΩ, then attempts should be made to reduce the impedance of the right mastoid electrode by removing the electrode, lightly abrading the skin and reapplying the electrode.

Large impedance differences between inverting and non-inverting electrode pairs degrade the common-mode rejection ratio (CMRR) of the preamplifier; that is, it reduces the ability to block EEG noise

components that are common to both electrode sites in a differential pair. The amount of reduction in CMRR increases almost proportionally with the impedance difference. When the impedance differences are too great, it can be difficult to achieve a satisfactorily low level of EEG noise for the ABR recording, despite the fact that the child appears quiet. When the baby is deeply asleep and the EEG is quiet, reduced CMRR may not matter, but when the baby is lightly asleep or dozing intermittently and the EEG noise is larger, reduced CMRR may lead to greater effects of EEG noise on the recording such that ABR testing may be unsuccessful in meeting EEG noise criteria (RN< 0.04 – 0.08 μV).

Careful attention to electrode impedance asymmetry is required. Given reasonable efforts to achieve satisfactorily low and symmetrical impedances, testing may proceed despite less than ideal conditions. The ABR Audiologist should document the impedance values and be alert to the possible need for a greater number of total sweeps and more frequent replication of records, should EEG conditions require it.

Higher but equal absolute impedances have negligible direct effect on CMRR, but they increase artifact voltage pickup due to electromagnetic (EM) current induction in the electrode leads or across the baby's scalp. EM current may be induced by any rapidly changing EM field surrounding the electrode leads, such as may be generated by AC 60-Hz power leads, outlets, switches, lights, dimmers or other nearby electrical devices. Fluorescent lights can be problematic because they produce higher harmonics of 60 Hz. Battery-powered LED lighting usually does not cause EM current induction and is readily available at low cost.

EEG and EM noise can be intermittent or change throughout a recording session. Thus, it is the ABR Audiologist's responsibility to make sure that the ongoing EEG is monitored throughout the session. If changes in noise are suspected and not likely due to the state of the infant, then a quick visual check of the electrode placements and impedances are recommended. Common challenges in impedance changes are electrodes falling off or making intermittent contact because they were not properly secured at initial setup or infant head movement caused the electrodes to shift.

3.6 RECORDING CHANNELS

For most ABR thresholds to AC tones, a single Electroencephalogram (EEG) recording channel is used, with the inverting electrode on the mastoid ipsilateral to the stimulated ear. For all BC-ABR measurements, two EEG recording channels must be used, with the high-forehead electrode referenced to each mastoid electrode, forming "ipsilateral" and "contralateral" channels.

For AC measurements, usually only the channel ipsilateral to the stimulated ear will be evaluated and plotted (see exceptions below). For BC measurements, 2-channel recording is mandatory, and both ipsilateral and contralateral channels will be evaluated and plotted.

ONE-CHANNEL (IPSILATERAL) EEG RECORDINGS (AC ONLY)

For ABR thresholds to AC tones, a single differential EEG recording channel is normally recorded and plotted, with the inverting electrode on the mastoid ipsilateral to the stimulated ear. In most cases, recording/displaying a contralateral channel has limited value, increases clutter and adds difficulty to waveform organization and rapid visual inspection.

TWO-CHANNEL (IPSILATERAL AND CONTRALATERAL) EEG RECORDINGS (ALL BC AND SOME AC)

For all BC-ABR measurements, two EEG recording channels must be recorded and plotted, with the high-forehead electrode referenced to each mastoid electrode, forming "ipsilateral" and "contralateral" EEG

channels. When stimulating by BC, the two EEG channels are necessary in order to resolve the responding cochlea; overall, ABR waveform morphology is better, with wave V typically peaking earlier and generally larger in the channel ipsilateral to the responding cochlea. This approach avoids several practical difficulties and unsolved questions related to contralateral masking of BC ABRs in infants.

For cases of substantially *asymmetrical AC thresholds,* two EEG recording channels (ipsilateral and contralateral) must be recorded and plotted. Asymmetrical AC threshold (at a specific frequency) is defined as either: (i) responses in one ear at the normal minimum intensity and the other ear threshold of ≥ 60 dB nHL or (ii) elevated thresholds in both ears and at least 40-dB threshold difference (in dB nHL) between ears. Like BC-ABR testing, 2-channel recordings allow comparison of ipsilateral and contralateral asymmetries in order to determine the responding ear.

For BC stimuli at all intensities and for AC stimuli at high intensities (usually at 80 dB nHL and higher), the presence of larger stimulus artifact in one EEG channel provides an indication of the laterality (i.e., which side) of transducer placement. Seeing much larger stimulus artifact in the "contralateral" EEG channel can flag stimulus or electrode errors. Similarly, two channels might reveal a stimulated ear or electrode connection error by showing a lateralized wave I on the wrong side. Standard procedures should be employed to protect against such errors; however, they do occasionally occur, and 2-channel recordings can aid in their detection.

3.7 TEST FREQUENCIES (AC AND BC)

The only test frequencies currently acceptable for use in BCEHP are (i) air conduction at 0.5, 1, 2 and 4 kHz, (ii) bone conduction at 0.5, 2 and 4 kHz.

The only stimulus conditions for which ABR normative threshold data, correction factors and clinical experience are acceptable for use in BCEHP are:

Air conduction: 0.5, 1, 2 and 4 kHz

Bone conduction: 0.5, 2 kHz and 4 kHz

AC tone-ABR thresholds may be measured only at nominal frequencies of 0.5, 1, 2 and 4 kHz, where 0.5, 2, and 4 kHz are mandatory, and 1 kHz is conditional. AC testing at other frequencies is typically not done because there are no adequate normative data for the relationships between ABR and perceptual (behavioural) thresholds at other frequencies for the type of stimuli specified in this protocol.

BC 2 kHz must be done if AC 2 kHz shows No Response (NR) at the minimum stimulus intensity. BC 0.5 kHz must be done if AC 0.5 kHz is the only elevation but is discretional if both AC 0.5 and AC 2 kHz are elevated. BC testing is not typically done at any frequency other than 0.5 and 2 kHz; BC 4 kHz testing should be considered if/when AC 4 kHz is the only threshold elevation.

In most cases, BC 4 kHz information is not required and should only be pursued after all mandatory requirements have been met. BCEHP research has determined (i) BC 4 kHz normal minimuim stimulus level (30 dB nHL) as well as (ii) a preliminary eHL correction factor (-5 dB). *BC 4 kHz is not mandatory as BCEHP is still collecting data from infants with sensorineural hearing loss.*

BCEHP is currently involved in research required to extend current AC 6 kHz (as well as BC 4 kHz) normative data and correction factors. Revisions to the current protocol may occur following completion of this research.

3.8 MINIMUM AND MAXIMUM STIMULUS INTENSITIES

With a few exceptions, normal minimum stimulus intensities for ABR are: (i) AC: 35, 35, 30 and 25 dB nHL at 0.5, 1, 2 and 4 kHz, respectively, and (ii) BC: 20 dB nHL at 0.5 kHz, and 30 dB nHL at 2 and 4 kHz. Maximum AC tone levels are 100 dB nHL; maximum AC click level is 90 dB nHL. Maximum BC tone levels are 50 dB nHL at 0.5 kHz and 60 dB nHL at 2 and 4 kHz.

Minimum stimulus intensities (i.e., normal) for ABR:

AC: 35, 35, 30* and 25 dB nHL at 0.5, 1, 2 and 4 kHz, respectively (*if elevated only at 4 kHz, 2 kHz must be tested down to 20 dB nHL)

BC: 20 dB nHL at 0.5 kHz, and 30 dB nHL at 2 and 4 kHz

Maximum AC stimulus intensities for ABR:

100 dB nHL at 0.5, 1, 2 and 4 kHz, respectively; these correspond to about 90-95 dB HL; *maximum* click AC level is 90 dB nHL

Maximum BC stimulus intensities for ABR:

50 dB nHL at 0.5 kHz and 60 dB nHL at 2 and 4 kHz (note that the B81 transducer can output higher levels, especially for the low frequencies)

The minimum stimulus intensities all equate to perceptual thresholds of about 25 dB HL, reflecting BCEHP-targeted hearing loss of 30 dB HL or more. Current normative data suggest that hearing levels below about 25 dB HL cannot be estimated accurately *without substantially increasing test times* (with little clinical gain).

The above minimum stimulus intensities do not represent the tone-ABR threshold of most infants with normal hearing. Indeed, most infants with typical hearing demonstrate responses to 20 dB nHL AC tones (52%, 96% & 100% for 0.5, 2 & 4 kHz, respectively; 92% at 30 dB nHL for 0.5 kHz) (Stapells et al., 1995). Similarly, most infants with normal cochlear function show responses to BC tones below the minimum intensities (0.5 kHz: 83% at 10 dB nHL; 2 kHz: 85% at 20 dB nHL; 4 kHz: 86% at 20 dB nHL) (0.5 & 2 kHz: Stapells, 1989; Stapells & Ruben, 1989; 4 kHz: ongoing BCEHP research). With few exceptions, however, it would be very inefficient (long testing time) and provide little extra clinical information for ABR audiometry protocols to test at levels below the normal minimum stimulus intensities. The exception to this is when there is hearing loss only at 4 kHz (i.e., responses for other frequencies are present at minimum stimulus intensities) where AC 2 kHz is now tested at 20 dB nHL. This additional testing is completed to accommodate accurate speech intelligibility index (SII) measurement.

Absolute maximum intensities for stimuli are determined by the upper limit of transducer linearity (AC and BC) and safety limits (AC). High-intensity testing can have implications with identification, management and counselling but must be used with discretion. **Only test at the maximum level (100 dB nHL for AC tone ABRs; 90 dB nHL for AC click ABRs) if there is a clear clinical need to do so (e.g., severe-profound HL and/or ANSD).** Switching frequencies and/or ears is a way to provide "rest" time for a cochlea.

3.9 AMPLIFIER GAIN AND MYOGENIC ARTIFACT REJECTION

Effective protection against large artifacts is critical and cannot be achieved by manual "pausing" of a recording. Currently, these ABR audiometry protocols set the rejection limits at ±10 μV. Without changing the gain, it is acceptable to reduce the rejection limits further to ±7 μV, provided rejected sweeps are no more than about 5-10% of total sweeps. Rejection rates greater than this are inefficient. Occasionally, rejection limits may be raised above ±10 μV but should be set at no more than ±25 μV (i.e., ±25%).

AMPLIFIER GAIN

A fixed preamplifier gain of 100,000 is usually appropriate. Gain should not be decreased if the EEG noise level increases during the test – smaller bad data are not better data. The proper course is to determine the cause of the increase in noise and make every effort to fix it at the source.

ARTIFACT REJECTION

Large myogenic artifacts in the ongoing EEG are the most common cause of inefficient and inaccurate ABR thresholds. Effective protection against large artifacts is critical and cannot be achieved by manual "pausing" of a recording. A few artifacts can instantly simulate a false ABR, abolish a real ABR or distort an ABR. The effective solution is to decrease the artifact rejection limits, moving them inward to a position such that even a quiet, ongoing EEG causes occasional sweep rejection. A general recommendation is that the gain and artifact reject level should be such that *no more than 5-10% of sweeps are routinely rejected* when the EEG is quiet.

Currently, these ABR audiometry protocols set the rejection limits at ±10 μV (i.e., 10% using 100,000 gain). *Without changing the gain*, it is acceptable to reduce the rejection limits further to ±7 μV, provided rejected sweeps are no more than about 5-10% of total sweeps (i.e., no more than 100-200 rejects during a 2000-sweep recording). Occasionally, rejection limits may be raised above ±10% (i.e., ±10 μV) to obtain no more than 5-10% rejected sweeps; however, the rejection level should not be raised to more than ±25% (i.e., ±25 μV).

Rejection rates greater than 10% of total sweeps are inefficient; if the number of rejects is higher than 10%, clinicians should attempt to improve the recording conditions.

Quiet EEG is highly desirable, but routinely obtaining averages with zero rejections usually reveals insufficient artifact rejection, resulting in measurements that are at high risk of response judgment errors, if artifacts occurred suddenly. Any infant may manifest high-amplitude myogenic bursts during a period of otherwise quiet EEG. Artifact rejection systems, even if set as just indicated, do not provide complete protection against such bursts, which may rapidly distort an otherwise clean average. Such bursts are preceded and followed by a few sweeps of high-amplitude activity that may not reach artifact rejection levels. At sweep acquisition rates of 21 or 39 per second, and faster, it is impossible to pause averaging fast enough to prevent this type of contamination; a good average that is either flat or is beginning to show a clear response can be contaminated irreversibly in less than one second. Once this has happened, it is almost impossible to undo the damage by continuing to add more sweeps (Figure 3.12.1). Reducing the artifact rejection so that only 5-10% of sweeps are rejected reduces some of this danger.

The above notwithstanding, careful and continuous monitoring of the ongoing EEG is essential through averaging; EEG amplitude increase should trigger immediate pausing of the averaging, which should then be resumed after a quiet EEG is re-established. Infants may manifest EEG with high myogenic levels even if they appear to be resting quietly or sleeping. It is the EEG activity that determines whether it is worthwhile to commence or continue averaging, not the child's overt behaviour. Should the infant's EEG deteriorate

substantially during the test, *the reason for an increase in myogenic noise levels must be dealt with at the source.* Actions include quieting or repositioning the child, moving cables, checking electrode impedances or simply waiting for the child to settle. It is strongly emphasized that if none of these actions are successful, the ABR test must be terminated because useful ABR threshold estimates simply cannot be obtained in the presence of large-amplitude active EEG. Obtaining no results is preferable to an incorrect interpretation based on noisy and non-replicable averages.

Under no circumstances should the artifact reject be disabled in order to permit averaging under poor EEG conditions.

3.10 ELECTROMAGNETIC 60-HZ ARTIFACT AND EEG NOTCH "LINE" FILTERING (ANALOG)

Interference from 60-Hz power sources is not unusual and is particularly problematic for 0.5 kHz testing. Checks are required to investigate sources of the electrical noise, electrode impedances and to ensure that electrodes and wire positions are appropriately located away from possible electrical noise sources. Often 60-Hz noise can be proven present by obtaining a no-stimulus (clamped-tube) recording. Sometimes a slight stimulus rate change (< 1-2/s) will substantially reduce the 60-Hz noise in the average. In extreme cases, the EEG "line" filter (which is a notch filter centred at 60 Hz) may be considered as a last resort.

Interference from 60-Hz (50-Hz in Europe) power sources is not unusual. ABR threshold estimates can be seriously compromised by the presence of power line artifact at 60 Hz. *Systematic procedures must be in place to minimize contamination of averages by 60-Hz power line artifact from sources within the test area.* Such artifact is usually sinusoidal with a typical period of about 17 ms (20 ms for European 50-Hz power sources). Power line artifact is most problematic for threshold measurements at 0.5 kHz, because of its similarity with the slow-wave component of the ABR to 0.5-kHz tone (as well as the 40-Hz auditory steady-state response). However, large 60-Hz interference can render averages uninterpretable or unreliable for any tone frequency (and even for click stimuli), and higher harmonics of 60 Hz may be present. The best fix for 60-Hz contamination of averages is to avoid or at least minimize it by controlling its sources and pickup.

When 60-Hz artifact is present, there is often an environmental or procedural issue that can be identified and addressed. To reduce problematic near-field 60 Hz EM radiation pickup, the baby and the ABR electrodes should be as far as possible from the closest live power outlet (used or unused) and essential power leads. Outlets that are never used should have metal cover plates. Non-essential power leads should not be plugged into outlets. Do not coil power cords; long cords radiate less EM when they are kept flat (i.e., on the same plane) and folded back-and-forth (like an accordion), rather than each fold or coil being on top of the preceding coil/fold.

Electromagnetic artifact pickup generally increases with larger area of the loop formed by the inverting and noninverting electrode leads, the baby's head and the SmartEP amplifier. The electrodes should be physically arranged to run as close together as possible to the SmartEP amplifier. In any given test area, changing electrode lead positions and orientations may change pickup levels significantly, but the absolute amount of pickup will vary from baby to baby, due to multiple factors, especially electrode impedance asymmetry.

The amount of artifact picked up by a differential electrode pair especially depends on the impedance difference between the two electrodes and the subject's scalp. The amplifier's ability to reject induced voltages at the two electrodes (CMRR) is drastically reduced by even minor asymmetries of impedance.

Averages always must be inspected for possible 60-Hz artifact. Suspicion is high if a smooth, slow wave is large and clearly begins in the first 10 ms of an average. **Often, 60-Hz noise can be proven present by recording a no-stimulus (clamped-tube) replication.** If suspected, the stimulus condition should be repeated immediately with the insert tube clamped or detached and moved away from the transducer. If the slow wave remains, then it is probably not a physiologic response. If the slow wave disappears, then it must be physiologic.

If 60-Hz artifact is present, efforts must be made to reduce electrode impedance asymmetries as well as to reduce the source of the artifact (e.g., dimmer switches, fluorescent lights); Sometimes, a slight stimulus rate change (< 1-2/s) will substantially reduce the 60-Hz noise in the average, essentially by "unlocking" the 60-Hz from the averaging by *slight* changes in the repetition rate (e.g., 39.1/s vs 38.9/s) and analysis sweep time. See example in Figure 3.10.1.

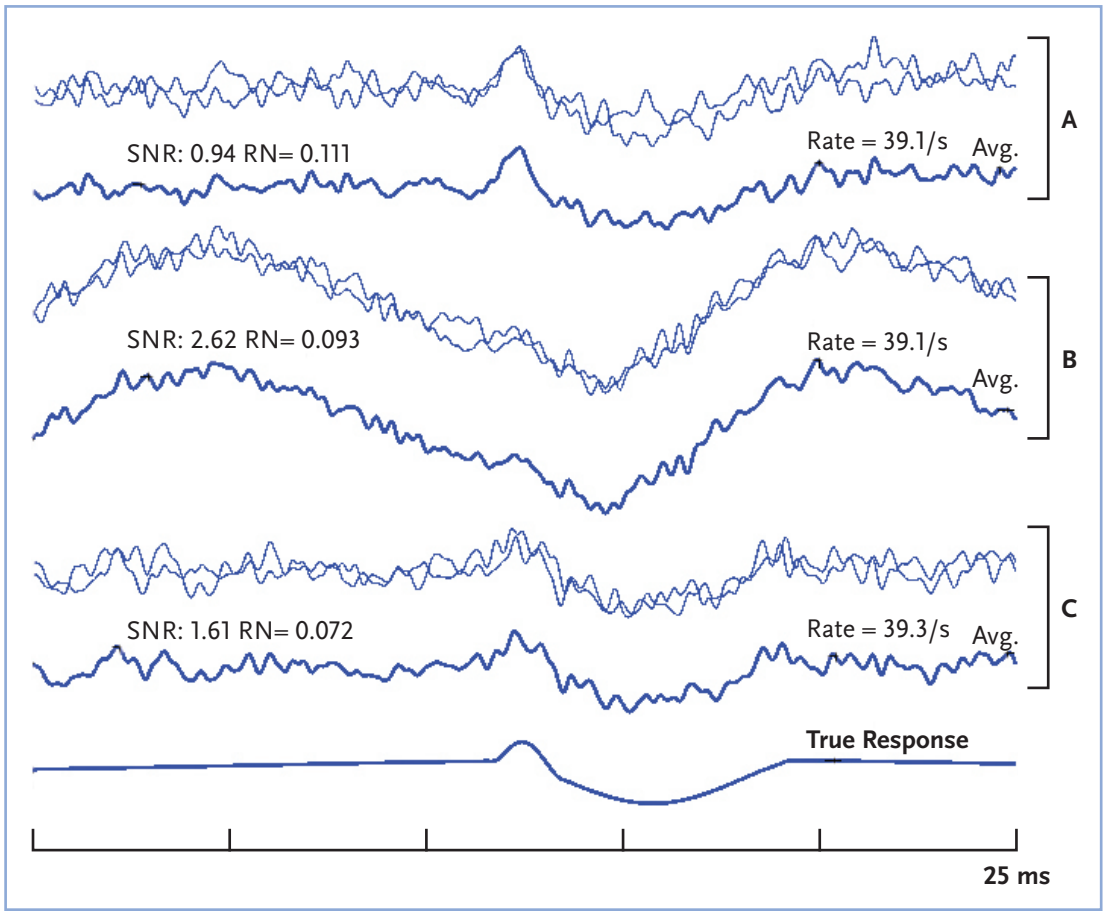


Figure 3.10.1: Changing stimulus rate slightly can reduce 60-Hz artifact. A: ABRs evoked by 0.5-kHz stimulus presented at a rate of 39.1/s without 60-Hz artifact contamination. B: ABRs evoked by a stimulus rate of 39.1/s with 60-Hz artifact contamination. It is difficult to identify the wave V peak in the trough (valley) of the large 60-Hz artifact. C: ABRs evoked by a stimulus rate of 39.3/s without 60-Hz artifact contamination. The underlying "true" response (ABR signal without EEG noise or 60-Hz artifact) is shown for these simulated ABR results at the bottom for comparison.

If large 60-Hz artifact cannot be eliminated, the 60-Hz line filter may be tried; comparison of recordings with and without use of a 60-Hz line filter will help confirm 60-Hz artifact presence versus a physiological response. This line filter, however, must not normally be used for threshold determination, as assessment by BCEHP indicates it reduces response amplitudes (on average about 15% with some larger reductions). Waveforms recorded without the line filter may also be digitally filtered offline to remove 60-Hz energy. This latter method is preferred over using the 60-Hz line filter.

The line filter may only be considered as a last resort if 60-Hz activity cannot be controlled (as may be the case when carrying-out ABR in operating rooms). If the EEG line filter or offline filtering is used, this must be noted on the ABR printout, and interpretation of the results should happen in consultation with a PSA.

If artifact problems are persistent, consultation with a BCEHP PSA is required.

3.11 WEIGHTED AVERAGING

Recent advances in clinical ABR equipment now include various forms of "weighted averaging", where low-noise sweeps contribute more (are given higher weighting) to the final average than do noisier sweeps. The IHS SmartEP has recently implemented weighted averaging. BCEHP will assess the use of weighted averaging for future protocol revisions.

Current non-weighted averaging procedures give equal weight to each sweep, regardless of its underlying noise level. For this type of averaging, noisier sweeps with amplitudes that are less than the artifact rejection levels are given equal weight as sweeps with very low-noise. Recent advances in clinical ABR equipment now include various forms of "weighted averaging", where low-noise sweeps contribute more (are given higher weighting) to the final average than do noisier sweeps (e.g., Don & Elberling, 1994; Elberling & Wahlgreen, 1985; Norrix et al., 2019). Implemented properly, brief bursts of EEG noise have little effect on the final average, and testing is faster because few sweeps are rejected (because artifact rejection limits can be increased). Results are better and testing faster with weighted averaging in infants who are occasionally noisy (no improvement is seen when infants are constantly quiet or constantly noisy). The IHS SmartEP has recently implemented weighted averaging. BCEHP will assess the use of weighted averaging. Based on this assessment, future revisions to these ABR protocols may include weighted averaging.

3.12 DIMINISHING RETURNS IN AVERAGING

The efficiency of averaging (signal-to-noise ratio improvement per unit test time) decreases rapidly as the number of sweeps increases. The first 1000-2000 sweeps are by far the most valuable in reducing noise. The longer the averaging time, the more likely the EEG will be contaminated by high-noise bursts, even with optimal artifact rejection.

Signal averaging is the primary technique employed to enable the detection and measurement of a small response (the ABR) in the presence of much larger background electrical noise (both biological and environmental). Using averaging, it is assumed the underlying ABR remains constant, whereas the EEG "noise" is random with constant variability over time. This means that as averaging of sweeps progresses, the noise (RN value) decreases and the SNR increases by the square root of the number of sweeps. There is a diminishing return on the investment in adding replications/sweeps: the larger the number of sweeps averaged, the smaller the improvement obtained by continuing to average. For example, as shown in

Figure 3.12.1, the RN for Noisy Subject #1 (blue line) drops by a large amount over the first 4000 sweeps averaged (RN reduced from 2.0 to 0.03 μV) but then much less so after 4000 to 8000 averaged sweeps (RN reduced from 0.030 to 0.025 μV). If the RN criterion to be able to detect a threshold response (or, alternatively, to determine NR) is 0.02 μV (dashed line in Figure 3.12.1, equivalent to 0.04 μV on SmartEP), then it would require more than 8000 sweeps to reach this criterion.

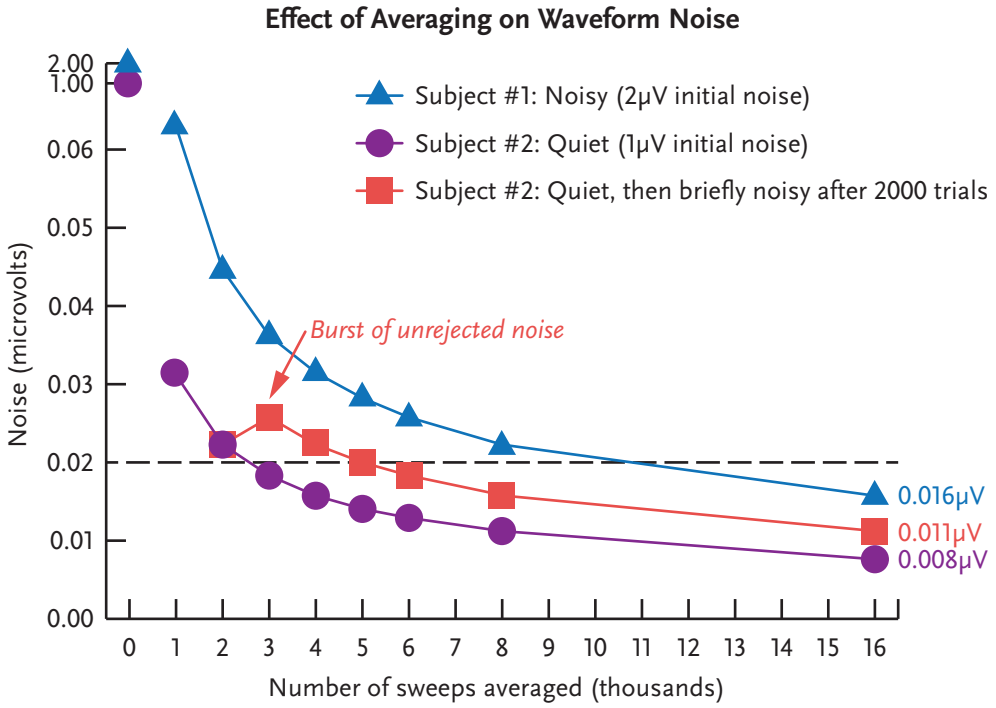


Figure 3.12.1: Waveform residual noise (in μV) as a function of the number of sweeps averaged, shown for a "quiet" subject (purple line), a "noisy" subject (blue line) and a quiet subject that is briefly noisy (red line). The dashed line represents a criterion of 0.02 μV (or 20 nanovolts). ***NOTE:*** *a real noise of 0.02* μV would be shown as *0.04* μV on the IHS *SmartEP (see Section 3.13 in text for explanation).*

In the previous section, it was noted that steps should be taken to minimize the noisiness of an infant's EEG. Reducing the noise in half will decrease the number of sweeps required by a factor of 4 (the root N law). Thus, in the example in Figure 3.12.1, if it is possible to quiet the infant and/or remove other electrical noise sources such that the initial noise before averaging is halved to 1 μV (purple line), then the criterion of 0.02 μV can be reached with fewer than 3000 sweeps.

Finally, if the infant briefly becomes noisy and this noise is included in the average, then the RN increases and more averages are required to reach the stopping criterion. This is illustrated in Figure 3.12.1; the burst of noise results in the need to acquire over 5000 sweeps to reach the stopping criterion, as shown by the dotted line. As discussed in the preceding section, the use of artifact rejection or weighted averaging removes or, at least, reduces the effect of this burst of noise.

The practical take-home points are:

- Averaging rapidly becomes less and less efficient the more you do it.
- The first 1000-2000 sweeps of an average are by far the most valuable in reducing noise. For this reason, current IHS set files are set to stop acquiring at 2000 sweeps.
- If things are not becoming clear by about 4000 to 6000 sweeps *within* an average, they will not become much clearer in that average within a practical amount of test time.

- The longer you average, the higher the likelihood of encountering a period of increased myogenic artifact, the impact of which will depend on how well you have set the artifact reject limits (or use weighted averaging). Even if the artifact is successfully rejected or weighted averaging implemented, it is still a period in which useful data are either not collected (artifact reject) or low-weighted (weighted averaging).

3.13 OBJECTIVE (ONLINE) MEASURES OF WAVEFORM RESIDUAL NOISE (RN) AND SIGNAL-TO-NOISE RATIO (SNR)

Modern ABR equipment provides measures of an accumulating average waveform's noisiness (RN, residual noise) and response signal-to-noise ratio (SNR). The ABR audiometry protocols specify maximum RN values in order to conclude NR (RN ≤ 0.08 µV or, in specific cases, RN ≤ 0.04 µV). Response Present (RP) is primarily determined subjectively/visually; however, a SNR of 1.0 or greater usually suggests a response is present.

Modern ABR equipment provides measures of a waveform's noisiness (RN) and signal-to-noise ratio (SNR) concurrent with averaging. Different brands of ABR equipment differ somewhat in the measures they provide. Currently, BCEHP utilizes the IHS SmartEP system, thus this protocol document will focus on the SmartEP RN and SNR measures.

The RN and SNR measures used by the IHS SmartEP are based on measures developed and assessed in the 1980s (e.g., Picton et al., 1983; Valdes-Sosa et al., 1987; Wong & Bickford, 1980); the use of these SmartEP measures for detecting infant tone ABR data obtained using BCEHP protocols were studied by Haboosheh and Stapells at UBC (Haboosheh, 2007). These measures are practically identical to those used by many clinical transient evoked otoacoustic emissions systems. When the IHS SmartEP records an average, it actually first records two subaverages ("Buffer A" and "Buffer B") alternating between even and odd-numbered stimuli. It uses the two buffers/subaverages to calculate the SNR and RN measures.

The SmartEP RN measure indicates the noisiness of the recorded average, expressed in microvolts (µV). The SNR measure is a measure of the average waveform's "size" compared to its underlying noisiness (indicated by RN). However, the way the SmartEP calculates the RN overestimates the actual noise by a factor of 2 [i.e., an IHS SmartEP RN level of 0.08 µV (or 80 nanovolts) is actually equivalent to 0.04 µV, or 40 nanovolts]. Because the IHS RN is double the "actual" noise level, the SNR calculation for IHS is half of the true SNR used in other ABR systems.[4] This difference is normally not an issue for clinicians, as BCEHP provides criteria for these measures specifically for the IHS SmartEP. However, this issue is important when: (i) the minimum SNR indicating a present response (the actual SNR would be 2 times the SmartEP calculated SNR, (ii) determining the minimum response amplitude that may be detected in a waveform with a specific RN (the "actual" RN is half what SmartEP indicates) and (iii) when comparing results with measures obtained using other brands of ABR equipment (e.g., Vivosonic and other manufacturer's may calculate the RN without the 2 times factor).

Research at UBC (Haboosheh, 2007), studies by Intelligent Hearing Systems and over 13 years of clinical experience at BCCH and BCEHP indicate that a SmartEP SNR of 1.0 *usually* indicates a response is present. However, expert human observers often detect a Response Present (RP) when SNR is less than 1.0 (e.g., 0.8 to 1.0); more rarely, these expert clinicians do not see a RP even with a SNR of around 1.0. These findings have led to the combination of subjective and objective response criteria presented in Sections 3.16 and 3.17.

[4] The noise is calculated from an estimate of the "±reference" (Schimmel, 1967). Created by obtaining the difference between two subaverages/buffers (each with half the number of averages of the overall recording), the IHS SmartEP incorrectly calculates this estimate by not dividing the resulting difference wave, the derived "±reference", by 2.

In order for an expert to detect a response waveform, the waveform peak-to-peak amplitude (e.g., wave V) typically needs to be at least 2.5 to 3 times the size of the actual RN level. At threshold, ABR wave V amplitudes are usually at least 0.1 μV (100nV), thus an actual RN of 0.040 μV (40 nV), which on SmartEP is equivalent to 0.08 μV, or lower is usually low enough to detect this wave V. Occasionally, however, threshold wave V amplitudes are as low as 0.050 μV (50 nV), and are easily obscured by noise (Don & Elberling, 1996; Bagatto, 2020). In this case, in order to detect these small responses, one requires an actual RN of 0.020 μV (20 nV) (SmartEP: 0.04 μV). *Thus, in order to not miss a threshold-level response, BCEHP criteria for NR require SmartEP RN to be ≤ 0.08 μV (or, in specific cases, ≤ 0.04 μV).* These criteria are described in detail in Sections 3.16 and 3.17.

The RN measure may be less useful in special circumstances, such as ABR audiometry undertaken in the Operating Room (OR). Excessive 60-Hz noise may be unavoidable in the OR, and the RN value may be high even with relatively flat ABR waveforms. On the other hand, the SNR measure can be artificially increased by the presence of stimulus artifact within the SmartEP "SNR region". BCEHP protocols have been designed such that the SNR region is placed beyond where most stimulus artifact occurs. However, SNR and RN calculations when testing BC 0.5 kHz at maximum stimulus intensities (i.e., ≥ 30 dB nHL) are problematic due to larger and, importantly, longer stimulus artifact at these levels. At these BC 0.5 kHz intensities, online SNR measures will not be reliable indicators of response presence. This is because the SNR region has been shifted to a later time interval in order to avoid including the longer stimulus artifact often seen while testing BC 0.5 kHz Hz at higher stimulus intensities. This shift sacrifices accurate SNR calculations in favour of obtaining accurate RN measurements.

3.14 NUMBER OF SWEEPS AND REPLICATE AVERAGES

For any test condition, an average of 1000 sweeps is the minimum. A maximum of 2000 per individual recorded waveform is recommended. With few exceptions, at least 2 averages (replications) per stimulus condition are required. Additional replications are often required.

Individual waveforms must not contain fewer than 1000 sweeps or more than 2000 accepted sweeps. The routine use of larger numbers of sweeps within an individual replication is discouraged because it is inefficient, due to the Root-N law of diminishing returns within averaging (Section 3.12). The overall number of sweeps can easily be increased by recording more replications and then combining them to obtain a grand-average waveform.

A minimum of two replications is required at any test condition, with additional replications often required (3 and occasionally 4). The exception to this is if the recording is not required to determine threshold (i.e., it is well above or well below threshold).

Although it might seem like a good strategy to continue averaging until the waveform RN reaches the 0.08 μV criterion level, regardless of response presence or absence, this is not an efficient strategy. Very often, a large and clear wave V, for example, may be seen well before the noise criterion is reached, often with an accompanying SNR ≥ 1.0. Thus, the requirement to reach noise criterion applies only to determination of NR.

Determination of response presence and the number of sweeps/replications required to make this determination must be made by the ABR Audiologist. If the response peak-to-peak amplitude is at least 2.5 times the actual RN and the SNR is at least 1.0, then averaging may be stopped after 1000 sweeps and a second (or third) replication initiated. In practice, most clinicians obtain 2000 sweeps per replication.

In select circumstances, if there is no response or a very small response, more replications may be required to either meet the RN and "visually flat" criterion for NR determination or to verify the presence of a very small response. However, in most cases, no more than 6 replications should be collected in order to reduce noise to meet RN criterion because of the exponential decrease in benefit from acquiring more replications.

3.15 CALCULATING "GRAND AVERAGE" WAVEFORMS

If response presence or absence is not clear, the "grand average" waveform must be calculated/provided for any single stimulus condition. The grand-average waveform must be calculated for any threshold-bracketing (upper and lower bound) conditions. Display the grand average below and separated from its corresponding replicate waveforms. The grand average waveform gives the best overall waveform estimate; however, the individual replications are important as they allow you to assess waveform reproducibility.

Two or more average waveforms for the same stimulus conditions must be combined to obtain a grand average if the individual waveforms do not immediately give a clear picture of response presence or absence. When this occurs, it will usually be at a threshold bracket or a minimum intensity level. Grand averages are always required for threshold bracketing conditions (upper and lower bound). The most effective way to display or plot the individual waveforms and the grand average for a given stimulus condition is as level-specific grouping with the grand average below the superimposed replications above. The grand average must never be superimposed on the primary averages, because this creates a false illusion of reproducibility. An advantage of displaying the grand average is that it is usually the best single sample estimate of the true waveform. Latency and amplitude measures are best made on the grand average (when calculated). Calculating the grand average is often most helpful when the individual averages are more variable, or for gaining a low RN when facing a marginal NR decision.

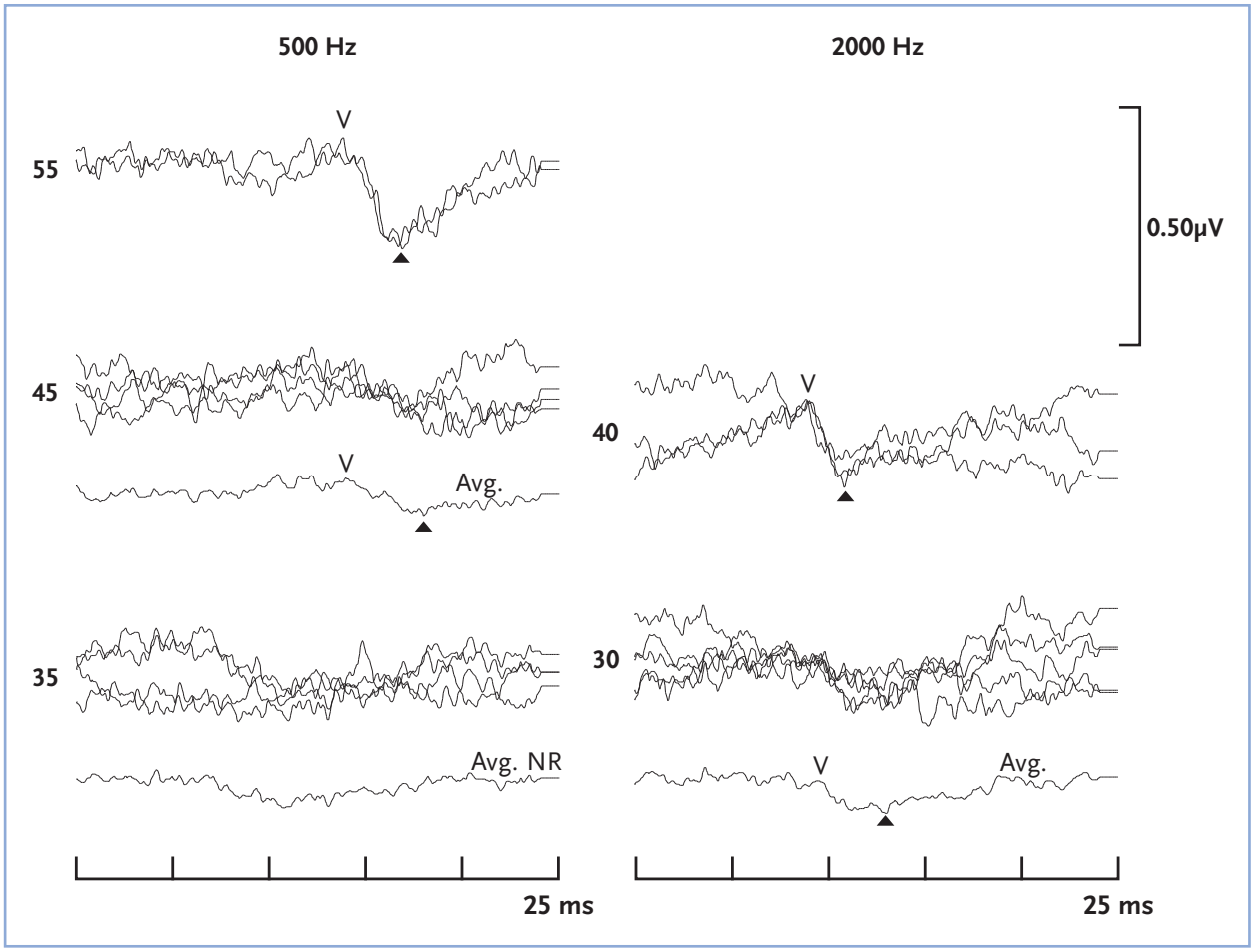


Figure 3.15.1: Calculating the grand average assists with response/NR determination. LEFT (AC 0.5 kHz): Two averages at 55 dB nHL show clearly replicable wave V. At 45 and 35 dB nHL, additional replications were required. The four superimposed replications at 45 dB nHL show a likely response; combining them to a grand average (AVG) shows a clear wave V (SNR=0.70; RN=0.09 µV). At 35 dB nHL, the four superimposed replications suggest NR but are somewhat noisy. Their grand average (AVG) is determined a NR, being flat in the wave V region (after 10 ms) with SNR=0.45 and RN=0.04 µV. RIGHT (AC 2 kHz): Three superimposed averages at 40 dB nHL show a clear wave V. At 30 dB nHL, the five superimposed averages suggest a wave V, which is then clearly seen in the grand average (AVG: SNR=1.95; RN=0.03 µV).

If three or more replications are available and one is *clearly much noisier* (e.g., much higher RN value) and thus very different from the others, in addition to the grand average of all replications, consider also calculating the grand average by combining only the low-noise averages and treating the noisy waveform as an outlier of questionable value. Reasons for leaving out a waveform from this alternative grand average must be noted on the recording sheet (particularly noisy waveforms are normally moved to "Page 9" on the SmartEP system).

As noted above, and visible in Figure 3.15.1, each of the individual averages is also an estimate of the true waveform but will usually have larger variability than the grand average. The individual averages are used to assess reproducibility of the response waveform. They also contain, both in their amount of amplitude fluctuation and in their associated RN, information about the underlying variability of the EEG in each of them. The grand average provides the overall SNR and RN after all replications have been combined.

SPLIT BUFFERS

As noted in Section 3.13, when the IHS SmartEP records an average, it actually first records two subaverages (Buffer A and Buffer B) alternating between even and odd-numbered stimuli. These subaverages are maintained when calculating grand average waveforms. The SmartEP provides the ability to "split buffers",

which displays the two subaverages underlying the grand average, providing replications each with half the total number of sweeps. When recording using alternating polarity stimuli (as required by BCEHP for tone-ABR), however, each buffer/subaverage represents a different polarity. As shown in Figure 3.15.2, viewing the "splits" provided by the SmartEP split buffers option can be very helpful when interpreting results, including assessing: (i) the replicability underlying the grand average of several replications (representing more sweeps, the buffers will have lower noise than individual replications), (ii) unexpected high RN and low SNR results for a clear waveform in the grand average, which may be due to presence of polarity-dependent responses such as cochlear microphonic (wave I region) and/or the frequency following response (wave V region), and/or (iii) unexpected waveforms, such as the wave I appearing response which is seen in response to higher intensity BC 2 kHz tones, but is actually due to asymmetry of the BC stimulus artifact (see Section 3.19).

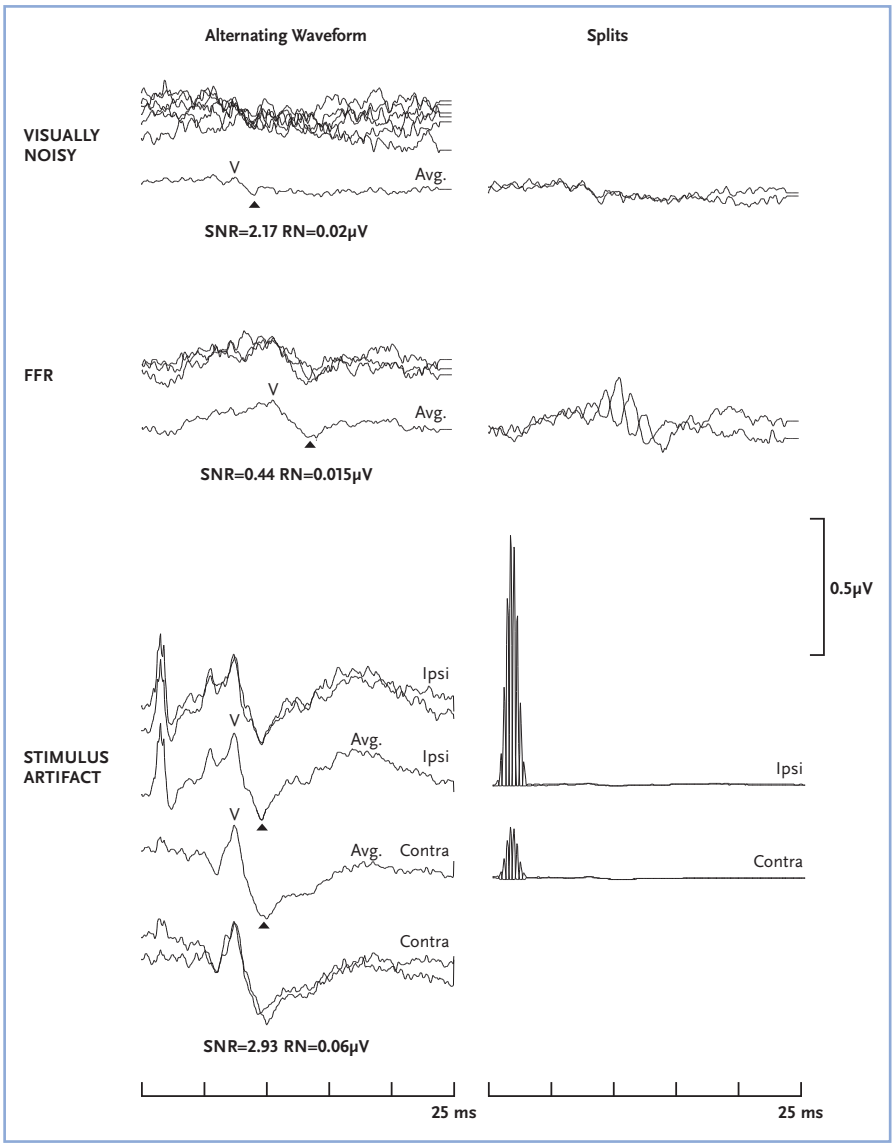


Figure 3.15.2: TOP: Individual waveforms are noisy, even though grand average (Avg) clearly shows a response. Splitting the grand average provides 2 replications (Splits), each with greater number of trials than the original replications, with wave V now clearly replicable. MIDDLE: Individual replications and grand average show clear wave V. However, grand average SNR is very low and RN very high. Splits clearly show these odd results are due to the frequency following response (FFR) overlapping wave V. The FFR changes according to stimulus polarity and thus is different in the A and B buffers when alternating polarity is used. Although the alternating polarity cancels the FFR, the SmartEP SNR and RN measures are calculated using the A and B buffers, thus the FFR results in a high RN. When the FFR is removed by filtering (not shown), the grand average shows a large SNR and small RN. BOTTOM: Sometimes, when recording responses to BC stimuli (or high-intensity AC stimuli), an early response is seen in the waveform which could be confused with ABR wave I. Observing the Splits demonstrates this early waveform is an artifactual result of the stimulus artifact being much larger for one polarity compared to the other. It is not wave I.

3.16 VISUAL ASSESSMENT OF RESPONSE PRESENCE/ABSENCE

Online objective measures of waveform RN and SNR remove some of the past subjectivity in judgments regarding EEG quality; nevertheless, there remains an important subjective aspect in judging EEG quality and response reliability. Therefore, for response presence, visual observation of replicated waveforms takes priority over objective measures, with the important exception that the grand-averaged waveform must reach a criterion RN ≤ 0.08 μV (or 0.04 μV) to conclude NR.

The interpretation of replicated waveforms relies on six main findings:

- the occurrence of a response-like waveform (e.g., ABR wave V) with expected morphology and latency for the stimulus frequency
- the prominence of the replicating waveform feature relative to the fluctuations in the remainder of the average (a visual SNR)
- the reproducibility of the feature across averages (a better measure of SNR)
- during averaging, observation of a relative lack of change in the supposed response compared to decreasing noisiness of the overall waveform is also suggestive of a true response
- assessed visually, the response peak-to-peak amplitude should be at least 2.5 to 3 times the average difference between the replications. The SmartEP RN measure may be used to provide an estimate of the waveform's RN, such that a RP will usually, *but not always,* show a peak-to-peak amplitude that is at least 1.25-1.5 times the SmartEP RN.[5]
- for NR, the IHS SmartEP RN must not exceed the 0.08 μV (or 0.04 μV, see below) criterion

Objective measures of waveform RN and SNR remove some of the past subjectivity in judgments regarding EEG quality; nevertheless, there remains an important subjective aspect in judging EEG quality and response reliability. Therefore, for response presence, visual observation of replicated waveforms takes priority over objective measures, with the important exception that the grand-averaged waveform *must* reach a criterion RN ≤ 0.08 μV (or 0.04 μV, see below) to conclude NR.

The morphology of the ABR to brief tones is very different from that seen in otoneurological ABR testing with click stimuli. Typically, the earlier waves of the ABR are absent and the response is a slow and later V-V' waveform (V' is the negative-going transition). There may be no "positive" wave V at all and only a negative V' peak. There may also be a positive-going deflection following V', at the end of the analysis interval. The ABR to 2 kHz usually shows a wave V that is more clearly defined and sharper than to 0.5 kHz, and the 4 kHz response can be quite similar to ABRs to clicks. In a normal tone ABR, the earlier waveforms (e.g., wave I, III) may be seen at normal minimum intensities, especially in response to 2 kHz and 4 kHz stimuli. The tone-ABR waveforms in Figure 3.16.1, recorded in an infant with normal results, are typical of the variety of waveform morphologies in response to brief tones.

[5] In order to capture a wide range of possible responses, as well as to conform to previous research using these measures, BCEHP sets the SmartEP "SNR regions" so that RN and SNR are calculated over a 10-ms window. In contrast, visual assessment of responses by experienced clinicians takes additional waveform factors into account (e.g., response morphology and latency) and often estimates the overall RN (replicability and difference between averages) over a shorter window length. Thus, an expert clinician may determine a RP even though the response peak-to-peak amplitude is not greater than 1.25-1.5 times the SmartEP RN measure. For the same reasons, a RP is sometimes determined even though the SmartEP SNR is < 1.

In general, the identified response should demonstrate similarity across averages, and the level of similarity in the expected response region should be greater than elsewhere in the averages. Waveforms that minimally change in morphology or amplitude during the online collection of the sweeps tend to be true physiological responses; however, large EEG and EM artifacts within a single initial sweep can also cause such stability. Thus, care must be taken to ensure artifact rejection limits are set appropriately. Waveforms that develop suddenly at any point during the course of averaging should be regarded with suspicion. In contrast, genuine responses can be rapidly obscured by small numbers of high-noise sweeps; this may happen frequently if the gain is insufficient relative to the artifact reject level.

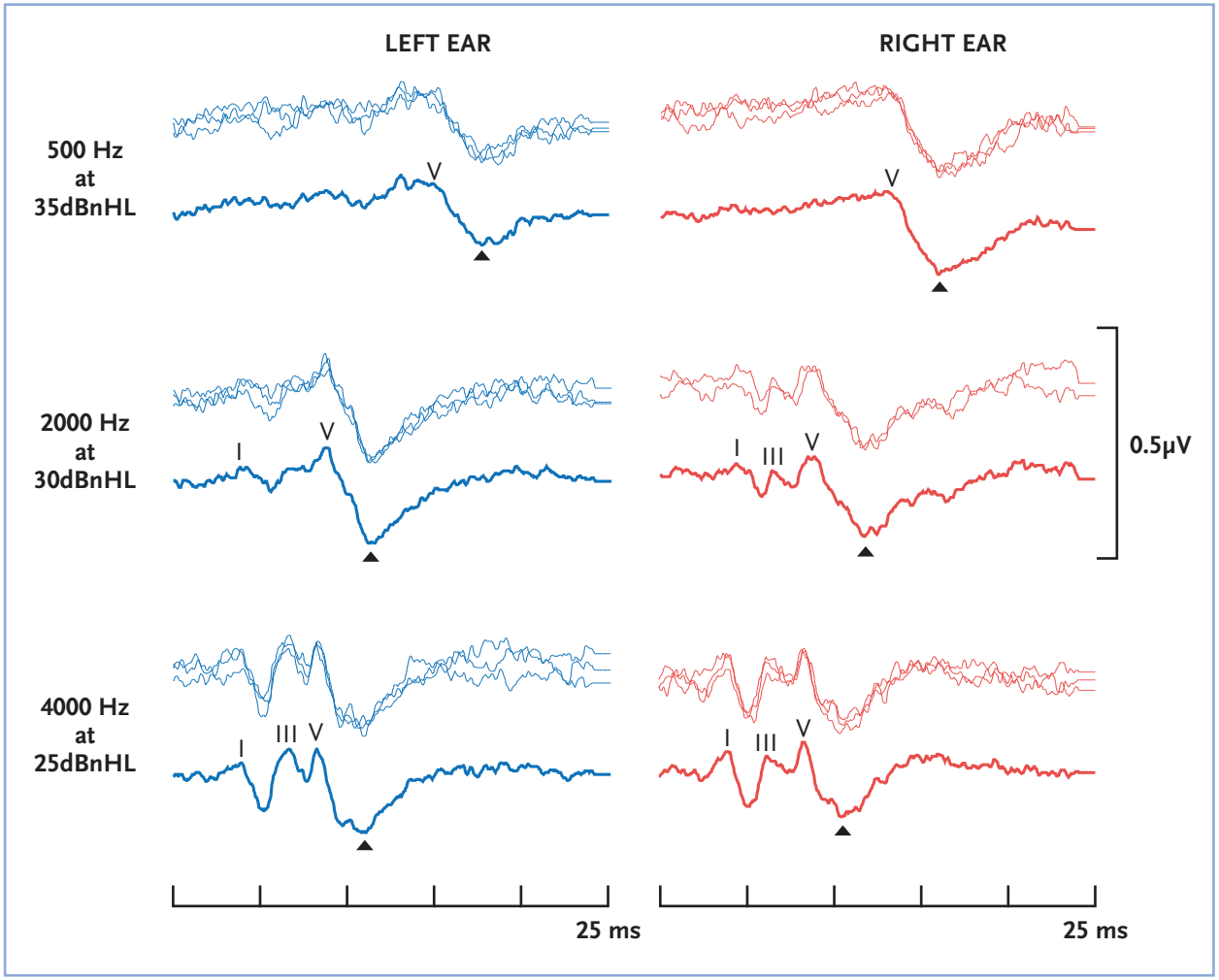


Figure 3.16.1: Typical normal AC-tone ABRs (replications and grand averages) recorded from a 5-week-old infant for stimuli presented at the "normal minimum" stimulus intensities for each frequency. Responses to low-frequency stimuli typically show only wave V-V'; responses to 4 kHz often also show earlier waves. For tone ABRs, only wave V latency/amplitude measures are required.

Occasionally, especially in response to tones, the recording may demonstrate a slow, somewhat cyclic (period < 15-25 ms), repeatable waveform which does not resemble wave V. Due often to the recording locking on to external electrical artifact, clinicians must determine whether it is a biologic response versus electrical artifact. A no-sound recording must be obtained by clamping the tube of the insert earphone (i.e., "clamped-tube run"). Changing the rate slightly often removes/reduces the electrical artifact (see above, Section 3.10).

3.17 RESPONSE JUDGMENT CATEGORIES

Three judgment categories are possible: "Response Present (RP)", "No Response (NR)" or "Could Not Evaluate (CNE)", with strict rules to conclude RP or NR. If neither RP nor NR can be concluded, then CNE must be indicated. CNE results are preferred to incorrectly concluding RP or NR; however, a CNE provides no clinical information.

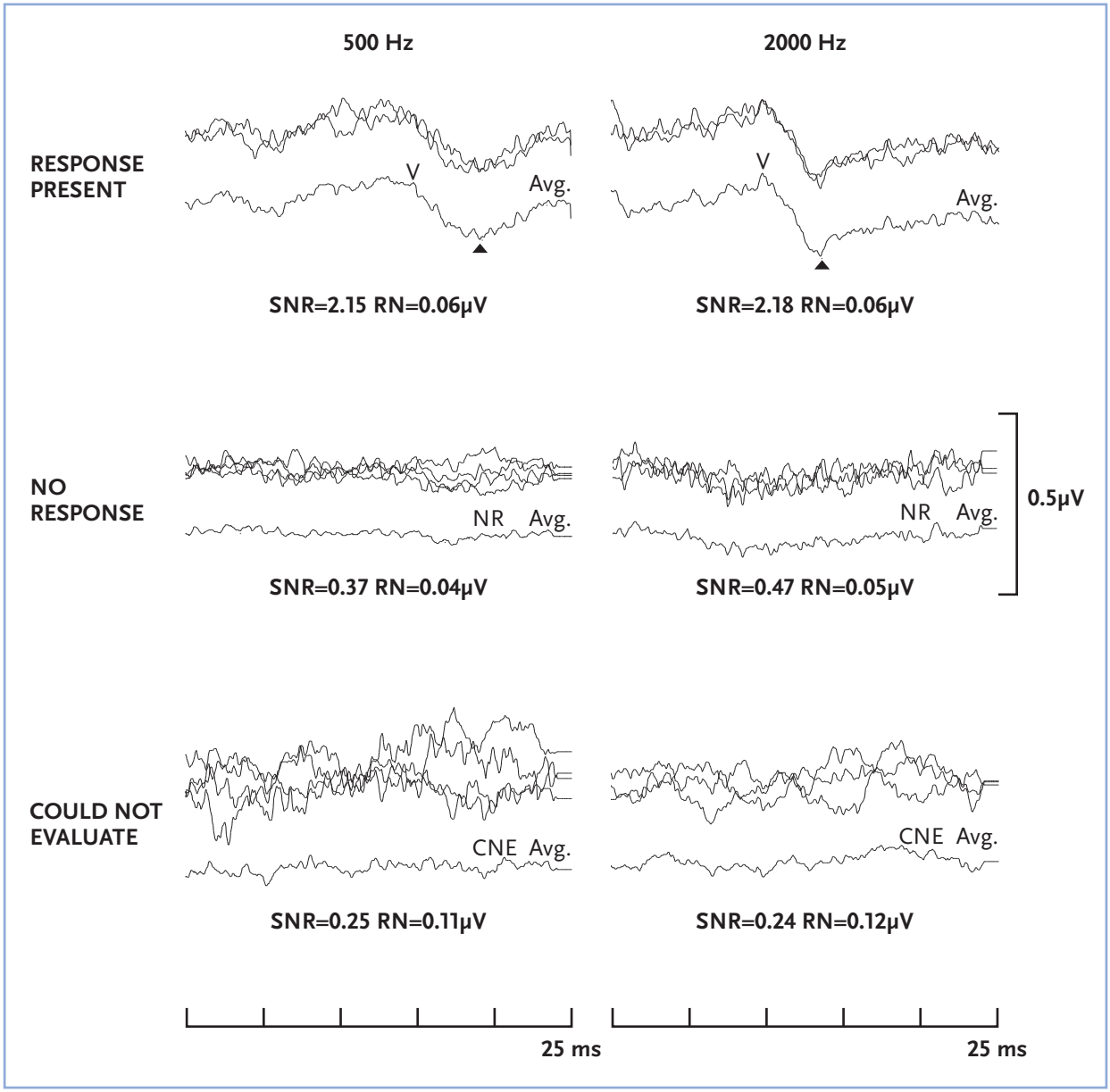


Figure 3.17.1: Response judgment categories and IHS SmartEP objective measures (SNR & RN).

DETERMINATION OF RESPONSE PRESENT (RP) REQUIRES THE FOLLOWING:

- **Repeatability**: Positive and/or negative-going deflections within the SNR interval that are judged to repeat across two or more replications, each replication with at least 1000 sweeps.
- Assessed visually, the **response peak-to-peak amplitude should be at least 2.5 to 3 times the average difference between the replications.** An RP will usually, but not always, show a peak-to-peak amplitude that is at least 1.25-1.5 times the IHS SmartEP RN (see below).
- Normally, the grand average will have a wave V with a positive and/or negative-going deflection with peak-to-peak amplitude of at least 0.05 µV to 0.1 µV (50-100 nV) (Don & Elberling, 1996; Bagatto, 2020) within the SNR interval determined by the stimulus frequency (see Appendix ABR4 for SNR region by frequency). Occasionally, when the RN is very low, one will detect a wave V with amplitude smaller than 0.05 µV; in this case, the wave V must be clearly repeatable with an appropriate latency and morphology.
- Latency and wave morphology should be consistent with (i) expected results for stimulus frequency and level, as well as subject age, and (ii) responses already obtained. (However, for tone ABRs, wave latency is not a criterion for present/absent or normal/abnormal.)
- A suspected response should have a peak latency that is at or delayed in comparison to a judged RP for the same stimulus/ear at any higher intensity.

Exceptions to the above exist for situations where the RP is deemed to be above ABR threshold. In this case, it is acceptable to interpret a single waveform (i.e., no replication) of only 1000-2000 accepted sweeps, provided the level is at least 10 dB above threshold and is not required to define threshold (see below), the single average shows an IHS SNR of at least 1.0 and the waveform shows a clear response that is typical/expected for the condition. *However*, if this intensity is subsequently determined to be required to establish (i.e., bracket) threshold, then the clinician must return to this intensity to obtain additional average(s).

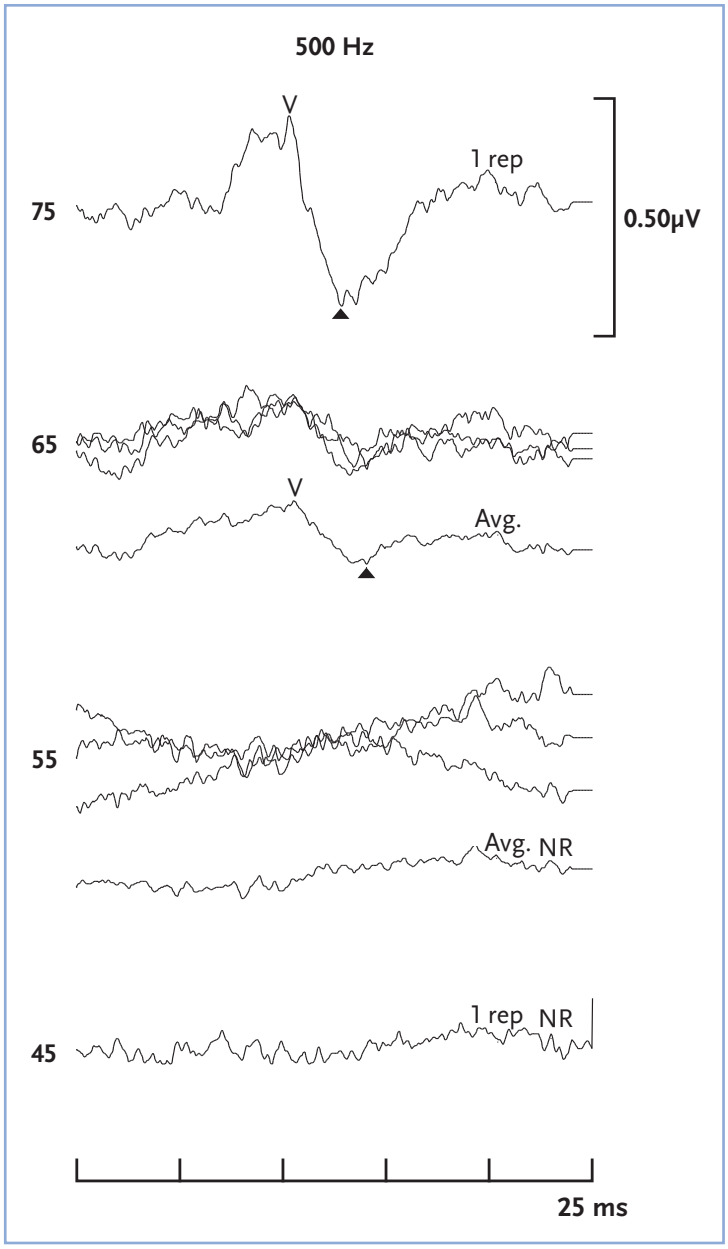


Figure 3.17.2: Threshold bracketing: Upper (65 dB nHL) and lower (55 dB nHL) bounds define threshold and require replications. Recordings above and below these bounds, in this case at 75 and 45 dB nHL, do not require replication provided they meet certain criteria (see text, Section 3.17).

NO RESPONSE (NR): RESIDUAL NOISE (RN) AND WAVEFORM "FLATNESS"

A threshold-level ABR wave V may be very small; thus, to be able to detect such a small response, the RN must be very low. In order to not miss small responses, BCEHP currently requires that any set of average waveforms judged to be NR must have a final RN (the RN of the grand average of the individual replications) no greater than 0.08 µV. Unfortunately, the RN measure can sometimes be low even in the presence of waveforms with low-frequency deflections/60-Hz interference. Thus, *subjective flatness (plotted at a reasonable scale, typically 0.5 µV, 25% plot size) of the grand average, in the SNR region where wave V-V' would be expected, and a RN ≤ 0.08 µV are mandatory for any NR decision.*

Occasionally, the recording may meet the RN≤ 0.08 µV noise criterion but include fluctuations which are not necessarily repeatable and do not resemble a wave such as wave V, but nevertheless appear large enough that they might make a small wave V impossible to detect. *In these non-flat ABR cases, in order to determine NR, additional replications must be obtained such that the RN is lowered to ≤ 0.04 µV, otherwise the condition must be rendered as Could Not Evaluate (CNE).* Thus, provided (i) RN≤ 0.04 µV and (ii) the non-flat waves do not look like wave V, the clinician can conclude NR (rather than CNE).

DETERMINATION OF NO RESPONSE (NR) REQUIRES THE FOLLOWING:

- two or more replications of at least 1000 sweeps each, *and*
- the SmartEP RN of the above replications **must be less than or equal to 0.08 µV**, *and*
- the **grand average of the replications must appear to be flat** within the SNR interval determined by the stimulus frequency. Note that wave V latency at a higher intensity can be used to determine the earliest wave V latency for lower intensities, and thus the region for flatness
- if waveforms are **not subjectively flat (and there is no clear Wave-V-like response), the SmartEP RN must be ≤ 0.04 µV to be determined NR** (i.e., RN must be reduced by obtaining additional replications).

In the above cases of NR, there should not be a RP obtained for the same stimulus at a lower intensity. Similarly, the SNR of the grand average for a NR result will be well below 1.0. If either of these occur, the clinician should carefully review their results.

Exceptions to the above exist for situations where the NR is deemed to be well-below ABR threshold. In this case, it is acceptable to interpret a single waveform (i.e., no replication) of only 1000-2000 accepted sweeps, provided the level is at least 10 dB below threshold, the RN is below the 0.08 µV noise criterion, the waveform is flat and shows no suggestion of expected waveform. *However*, if subsequent testing indicates this intensity is required to determine (i.e., bracket) threshold, then the clinician must return to this intensity and obtain additional average(s).

DETERMINATION OF COULD NOT EVALUATE (CNE)

If neither RP nor NR can be concluded from the set of waveforms for a given condition (stimulus frequency, level, ear, etc.), then a conclusion of CNE must be indicated.

CNE results are preferred to incorrectly concluding RP or NR. However, a CNE provides no clinical information. The most-common reason for CNE results are combinations of (i) infants not quietly sleeping, (ii) insufficient averaging and (iii) inefficient test strategy. A focus of BCEHP training and support is to reduce the number of CNE results.

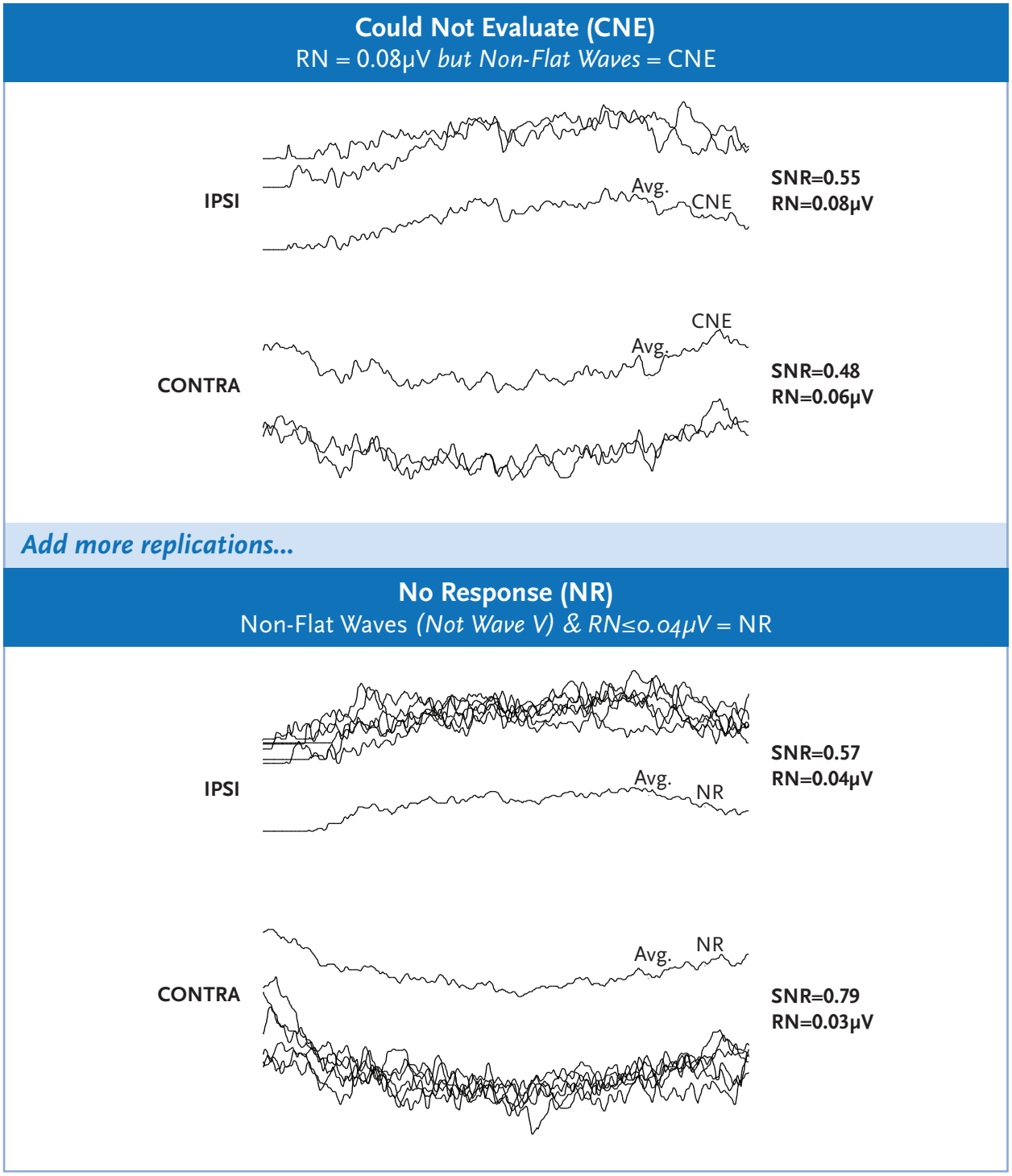


Figure 3.17.3: When "non-flat" waves obtained (in response to 2 kHz stimuli), recording to RN of 0.08 μV is not sufficient to conclude NR (hence one must conclude CNE). In order to conclude NR with non-flat waves (but no clear wave V), one must record enough sweeps so that the RN is ≤ 0.04 μV.

3.18 MEASURING ABR WAVEFORM LATENCY AND AMPLITUDE

Measures of wave V latency and amplitude must be made for responses to tones; measures of wave V latency and amplitude and, if present, wave I latency and amplitude are required for responses to clicks. Guidelines for these measures are provided. Additional measures for clicks are required as part of the ANSD/retrocochlear subprotocol (see Section 5).

RESPONSES TO TONES

Measurement of wave V latency and amplitude must be made. These measures are easily (and best) made on the grand average of the replications (see, for example, Figure 3.16.1); however, for tone ABRs obtained at levels above threshold brackets (where grand averages are not required), it is acceptable to make these measures on one of the replications by visually estimating the average latency/amplitude across the replications. Measurements of any earlier waves, when present, are discretional for responses to tones.

Wave V latency and amplitude measures for responses to tones aid in interpreting response presence/absence at different intensities (and frequencies). They are especially important for assessing ipsilateral vs contralateral cochlear contributions in response to BC stimuli (and, occasionally, in response to high-intensity AC stimuli).

The range of possible latencies in response to tones is so broad that using specific targets ("norms") for latency is unhelpful, thus the *"normality" of tone-ABR latencies is not determined* (i.e., they are not compared to "normative" data). Nevertheless, *changes* in latency as a function of stimulus intensity and/or frequency for an individual infant can assist the clinician in distinguishing true responses from background EEG noise: (i) as intensity is decreased, wave latency increases – thus, responses to 60 dB nHL stimuli should not be earlier in latency as those to 80 dB nHL stimuli; and (ii) as stimulus frequency is decreased, wave latency increases – thus, at the same intensity, responses to 0.5 kHz tones are typically later than responses to 2.0 kHz tones. This latter relationship (latency vs frequency), however, can substantially change when significant hearing loss is present.

RESPONSES TO CLICKS

Measures of wave V latency and amplitude and, if present, wave I latency and amplitude are required. When present, measurement of wave III latency is optional. Additional measures, including measurement of the cochlear microphonic, are required as part of the ANSD/retrocochlear subprotocol (see Section 5). The wave-I-to-wave-V interpeak latency ("I-V IPL") is automatically calculated by the SmartEP when both waves are measured and should be compared to appropriate normative data (Appendix ABR6); abnormality should be indicated if greater than 3 standard deviations from the normal mean.

WAVE V MEASUREMENT (TONES AND CLICKS)

Wave V latency is normally measured as the "last point" (i.e., on the shoulder of the peak) before the large negative deflection (not the midpoint of the positive wave). Wave V amplitude in response to tones is measured to the largest negative amplitude within 8 ms following the wave V latency measure, regardless of the presence of any intervening peaks (Figure 3.18.1). Wave V latency and amplitude measures to clicks are similar, except that Wave V amplitude is measured to the largest negativity within 6 ms following wave V latency (Figure 3.18.2).

WAVE I MEASUREMENT (TONES AND CLICKS)

Wave I is often seen in responses to 4 kHz tones, occasionally to 2 kHz tones, and rarely (if ever) to 0.5 kHz tones. When made, wave I latency is measured in the middle of the peak and amplitude is made to the largest negativity within 2 ms following wave I latency (regardless of any intervening positive peak). The same measurement rules apply to responses to clicks (Figure 3.18.2).

WAVE III MEASUREMENT (TONES AND CLICKS)

Wave III is usually the most prominent peak occurring approximately midway between waves V and I. However, measurement of wave III is problematic, as this wave is often "double-peaked", such that choosing the latency of the first peak may be too short, whereas choosing the second peak may be too long. It is not always clear which peak to measure, though comparison of results for rarefaction and condensation clicks may help. Sometimes simply choosing an arbitrary point in the middle of the two peaks can make sense. This is especially an issue for responses to clicks; thus, wave III measures provide low clinical value for ABR testing within BCEHP and are thus discretional.

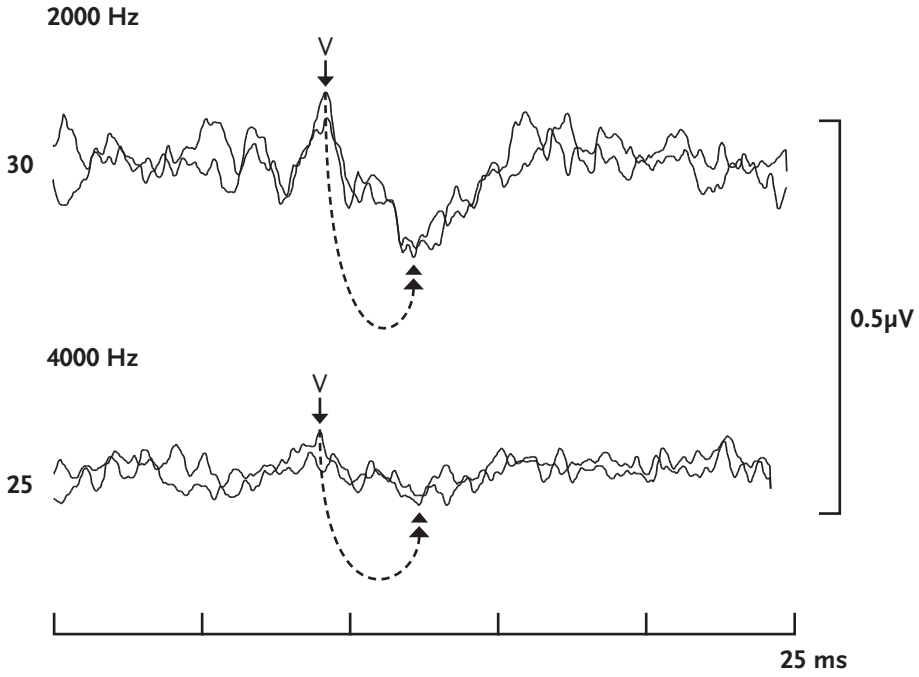


Figure 3.18.1: Tone ABR: Measurement of wave V latency and amplitude. Wave V amplitude is measured to the largest negativity occurring withing 8 ms of wave V latency (ignoring any intervening waves, as shown in these examples).

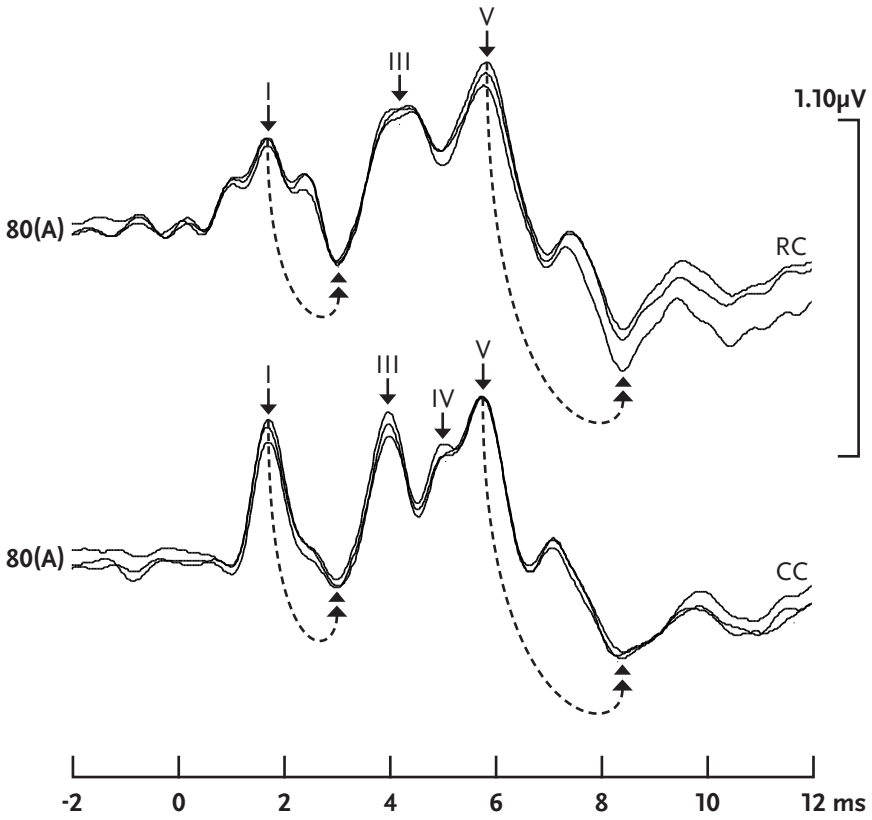


Figure 3.18.2: Click ABR: Measurement of wave I and V latency and amplitude to rarefaction (RC) and condensation (CC) clicks (80 dB nHL). Wave I amplitude is measured to the largest negativity occurring within 2 ms of wave I latency (ignoring any intervening wave II). Wave V amplitude is measured to the largest negativity occurring within 6 ms of wave V latency (ignoring any intervening waves, as shown in the examples). Waveforms are plotted using a -2.0-ms pre-stimulus start-time.

3.19 STIMULUS ARTIFACT IN ABR TO BC (AND HIGH-INTENSITY AC) STIMULI

Large stimulus artifact is often present in responses to BC stimuli. However, BCEHP protocols specifically set artifact rejection and SNR regions to exclude stimulus artifact and use alternating polarity for tone stimuli, thus stimulus artifact is generally not a problem.

Stimulus artifact ringing can sometimes interfere with waveform interpretation at high stimulus intensities for both AC (90-100 dB nHL) and BC (≥ 40 dB nHL) stimuli. Averaging waves from alternating stimulus polarities (rarefaction and condensation) removes most stimulus artifact issues due to ringing; however, at high intensities, the transducers usually show asymmetry in stimulus artifact amplitudes and ringing between rarefaction and condensation polarities. This results in uncancelled stimulus artifact even after averaging across the two polarities (i.e., "alternating" polarity), which sometimes causes difficulties in response interpretation. Special consideration should be taken when interpreting ABR waves in response to high stimulus intensities for AC (90-100 dB nHL) and BC (≥ 40 dB nHL) stimuli.

Appropriate procedures to minimize BC stimulus artifact must be used. The most important steps are routing transducer leads/wires and electrodes as far as possible from each other, keeping electrode leads/wires close together and pointing away from the transducer, and minimizing differences in electrode impedances as noted earlier (see Sections 3.4 and 3.5). Placing the mastoid "inverting" electrodes low

on the mastoids and their leads/wires pointing down the neck and away from the BC transducer helps to reduce stimulus artifact issues.

Using the IHS SmartEP, BCEHP parameters are designed to: (i) reduce sweep rejection caused by stimulus artifacts (by setting artifact rejection region after the stimulus artifact), (ii) reduce stimulus artifact by using alternating stimulus polarities (rarefaction and condensation) and (iii) reduce contamination of objective measures (RN, SNR) by setting SNR regions to avoid stimulus artifact.[6]

Uncancelled high-amplitude BC stimulus artifact can appear in the average alternating recordings, especially at 0.5 kHz, and at the highest stimulus levels available, which are typically 50 dB nHL for BC 0.5 kHz and 60 dB nHL for BC 2 and 4 kHz. The IHS SmartEP RN and SNR measures may be contaminated and therefore are unreliable when significant stimulus artifact is present. Significant artifact also occurs with high-intensity AC stimuli, such as 100 dB nHL stimuli. For this reason specifically, alternating stimulus polarity must be used for BC stimuli. Even with alternating the stimulus polarity, however, artifact is not entirely removed due to asymmetry of the BC transducer response with stimulus polarity inversion. For BC 0.5 kHz, the problem is that stimulus artifacts can extend into a substantial portion of the analysis epoch and can sometimes make reliable ABR V-V' identification difficult. Nevertheless, in the majority of cases, wave V-V' remains identifiable.

An even larger problem is that BC 0.5 kHz stimulus artifact can (and does) contaminate the online RN measure *if correct SNR regions have not been set up prior to testing*. When testing BC 0.5 kHz at 30 dB nHL and above, the SNR region must begin later (Appendix ABR3), such that it may miss all or part of wave V-V'; hence, for BC 0.5 kHz at these levels, only the RN measure is accurate. A separate SmartEP .SET file reflecting the later SNR should be used for BC 0.5 kHz at intensities of ≥ 30 dB nHL.

For BC 2 kHz testing, uncancelled stimulus artifact may result in an early waveform that could be misinterpreted as "wave I" (Figures 3.19.1 and 3.20.4). Evaluation of the rarefaction and condensation sub-averages, made possible using the IHS SmartEP split buffer routine, will usually indicate that the wave I is actually caused by asymmetric (and thus only partially cancelled) stimulus artifact. ABR Audiologists must be careful to differentiate this artifact-created result from a real wave I, which might indicate a neurologic or ANSD problem.

[6] Although available on the IHS SmartEP, the ability to set the artifact rejection region to begin *after* the stimulus ends is not available on all manufacturers' ABR systems. When this feature is not available, the presence of large stimulus artifact causes rejection of most/all sweeps; the only option in this case would be to turn off the artifact rejection.

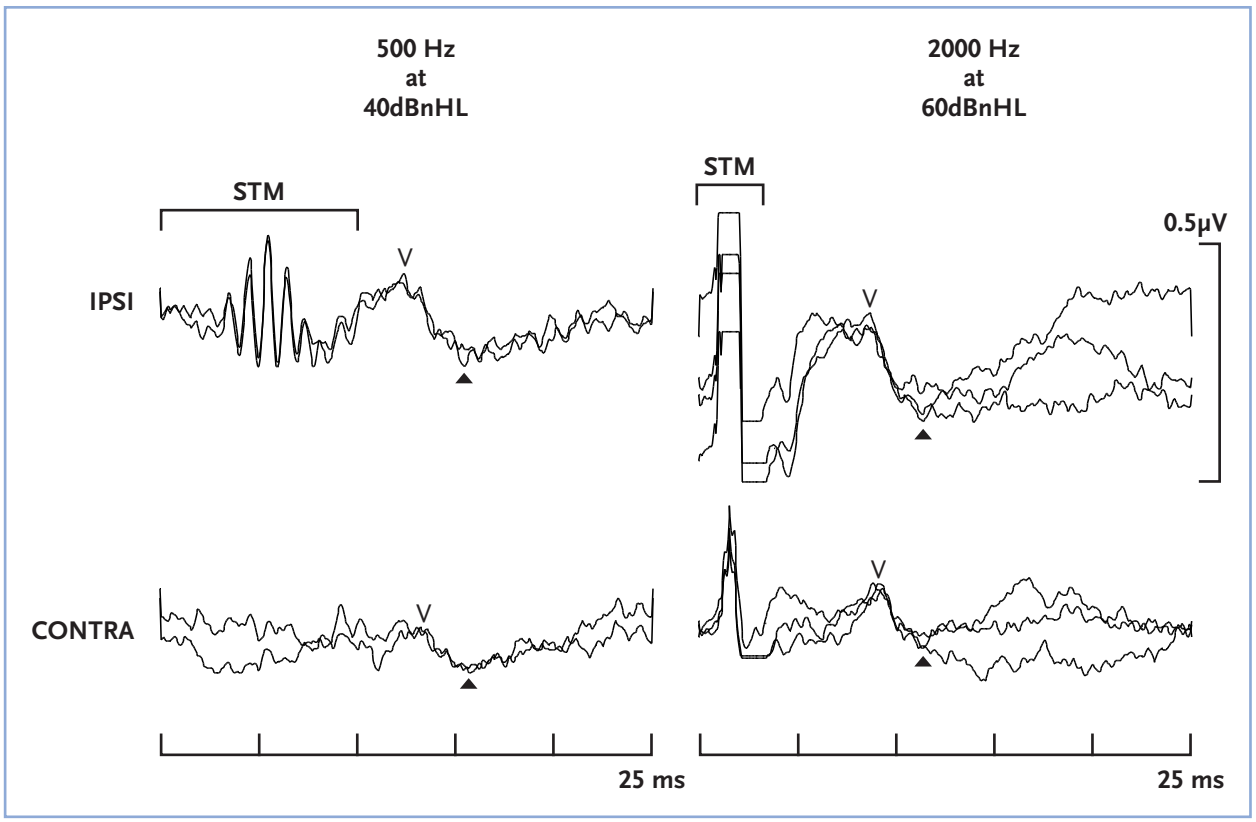


Figure 3.19.1: Stimulus artifact in the ABR to moderate-intensity BC tones. The region of artifact is denoted by "STM". The presence of large STM does not affect the identification of wave V. Artifact is normally substantially larger in the EEG channel ipsilateral to the bone transduce placement. However, as shown in the BC 2 kHz responses, it can sometimes be present in both channels. Clinicians must be careful not to (mis)interpret the BC 2 kHz STM artifact as ABR wave I.

If stimulus artifact problems persist, they are usually reduced dramatically by lowering the stimulus level by 5-10 dB, because artifact size is directly proportional to the stimulus voltage (a 10-dB change results in a threefold change in stimulus artifact; a 6-dB change results in a 50% change).

3.20 ABR RECORDING SHEET AND ABR DISPLAY REQUIREMENTS

Consistent ABR Recording Sheet notation and organization of waveform printouts is required, as they facilitate rapid visual inspection and interpretation, as well as review by other persons such as colleagues, BCEHP PSAs and/or the BCEHP CQI Panel. Waveform display samples are provided.

ABR RECORDING SHEET

Consistent choice of notations must be used on the ABR recording sheet *during* the ABR audiometry session. For each stimulus/ear condition, the file name and basic recording parameters (ear, intensity, stimulus and channel) must be recorded for the first occurance of that combination. For subsequent repetitions, only the file number is required. In addition, for each group of stimulus/ear condition, there must be one overall online judgment, annotated as either "RP" or "✓" (Response Present), "NR" or "X" (No Response) or "CNE" (Could Not Evaluate) whenever either RP or NR cannot be determined. When test conditions or results are suboptimal/challenging, additional notes may be helpful. See Appendix ABR1 for the ABR recording sheet (also on BERT).

ABR WAVEFORM DISPLAY

Consistent organization of waveform printouts facilitates rapid visual inspection and interpretation, as well as review by other persons such as colleagues, BCEHP PSAs and/or the BCEHP CQI Panel. It also expedites any type of review, including training or updating reviews, consultations, second opinions, standard performance reviews or adverse event audits. Therefore, a standard format is mandatory. Details are provided in this section, along with examples.

ABR PAGE SETTINGS (IHS SMARTEP):

- Averages should be displayed half page width (split page mode), with two columns of waveforms typically forming a page; left ear results are usually displayed on the left of the page and right ear results on the right, unless specified by a label on the top of the page.
- Waveforms are usually shown at a page scale of 0.5 µV and 25% plot size; however, on rare occasions, the page scale may need to be modified to accommodate large waveforms. For example, this may occur when testing high-level clicks in a child with normal tone-ABR results.

The frequencies tested, grand averages calculated and wave V responses (including V-V' latency and amplitude measures) must be provided. Averages are grouped by ear and frequency within each ear. When multiple frequencies are displayed on one page, the waveforms should be organized so that the lowest frequency is on the top of the page and the highest frequency at the bottom. All replicated waveforms must be superimposed. If calculated, the "grand average" waveform for each group of averages must be displayed directly below its corresponding replicate waveforms. Labels identifying the condition tested (e.g., 0.5, 1, 2 and 4 kHz) and the grand average waveform (abbreviated below as "Avg") are required. The following example waveform printouts are intended to demonstrate waveform display requirements.

In each ear, for any single stimulus (e.g., AC 2k 60 dB nHL), there will be two or more replicate waveforms but *only one overall judgment* of ABR presence or absence that applies to the entire set of averages at that given level, aided by defined criteria. Response detection judgments must be categorized as: (i) RP, with wave labels, such as "I", "V", "CM" and/or "PAMR" (post auricular muscle response), being placed above the key peak on the ABR waveform that is judged to be present; (ii) NR; and (iii) CNE. RP and NR decisions reflect high confidence; CNE decisions are implemented when either RP or NR cannot be determined with confidence. A program-wide standard approach is required; only these notations may be used.

ABR display example: Normal hearing (AC only)

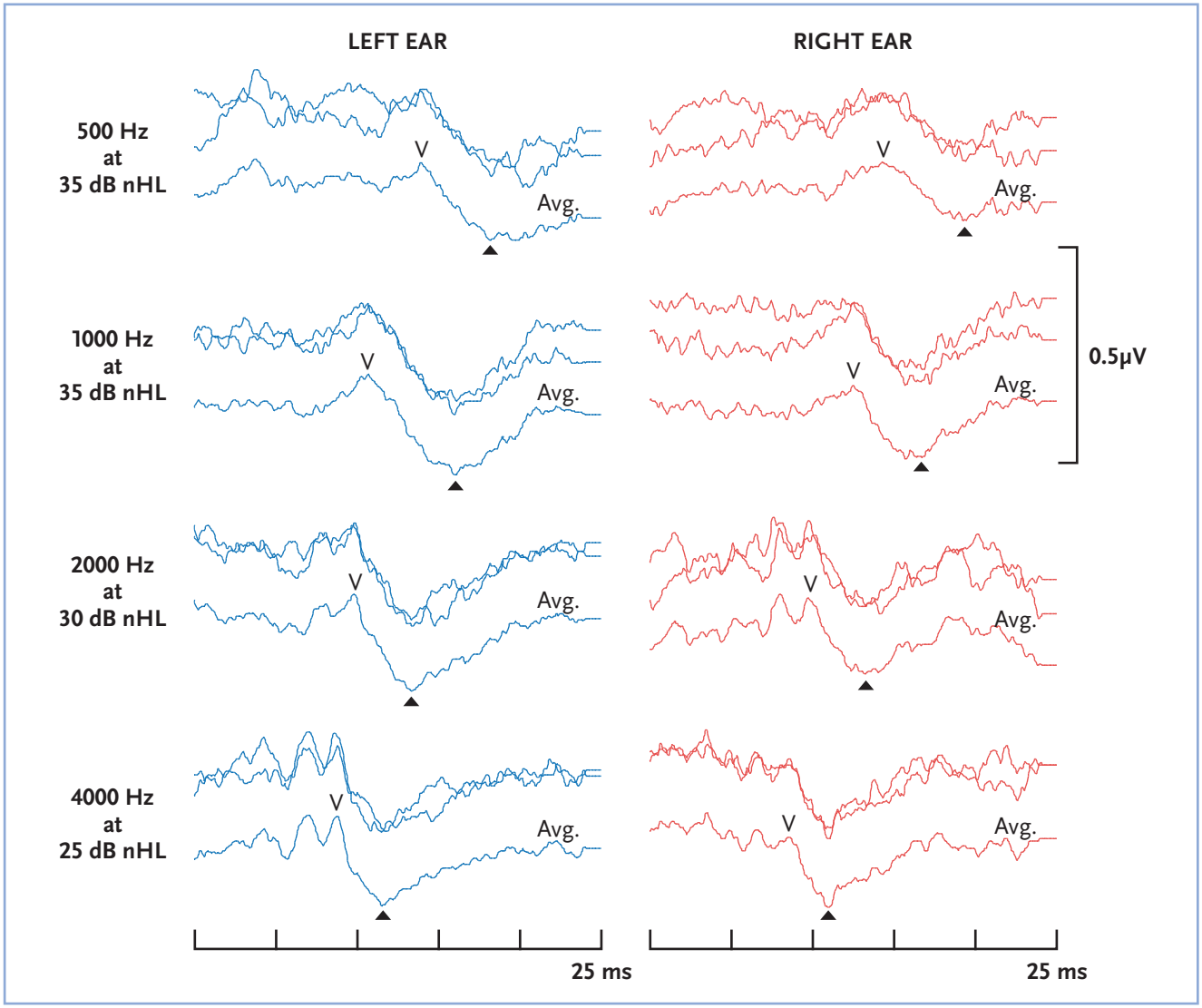


Figure 3.20.1: Example ABR displays for left (blue) and right (red) ears for air-conduction ABR results at "normal" minimum intensity levels.

For any condition where multiple intensities have been tested (AC and BC), averages are ordered by descending intensity within each ear and frequency. For each test frequency and stimulus route, waveforms should be *superimposed* by descending intensities. Calculation of the grand average is required for any (1) threshold-determining conditions (upper and lower bound) and (2) sets of replications that are noisy and for which no individual replication best represents the group. The grand average is important to confirm the overall tracings are flat and meet RN criteria, as it can be difficult to visualize flatness in replications without seeing the grand average. Calculation of the grand average is discretional for non-threshold bracketing conditions. Note that the grand average must be calculated with the proper setting file loaded in order to display correct SNR/RN values (i.e., calculated using the correct SNR Region).

ABR display example: Elevated threshold AC results

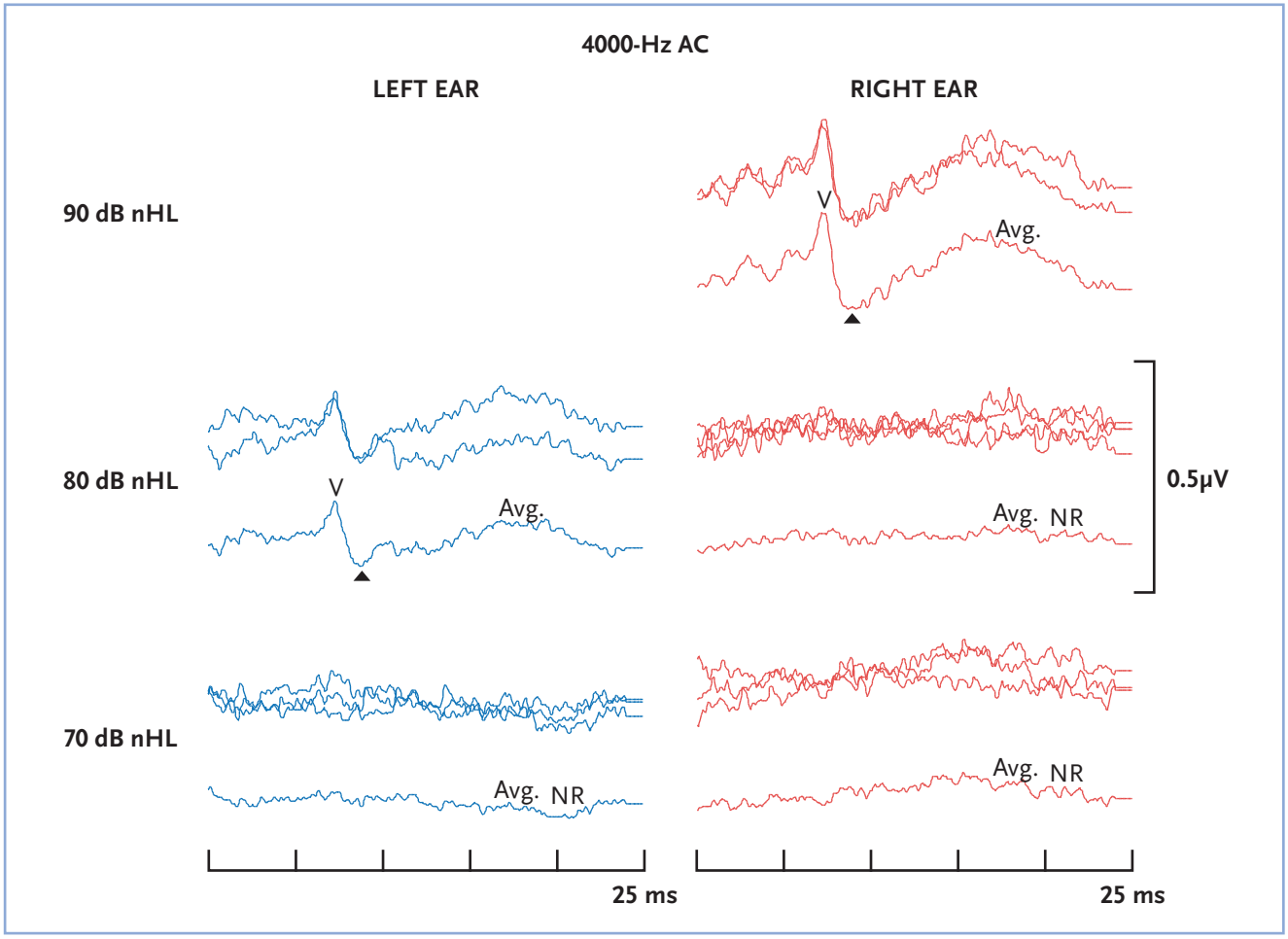


Figure 3.20.2: Example of air-conduction intensity series (elevated threshold) for the left (blue) and right (red) ears.

For BC recordings, and any 2-channel AC recording, for each stimulus level, the ipsilateral waveforms must be grouped separately from the contralateral waveforms, with the ipsilateral group of replications plotted immediately above the contralateral group. If calculated, the "grand average" waveform for each group of 2-channel averages must be displayed directly below (if ipsilateral) or above (if contralateral) their corresponding replicate waveforms. The plotting should be in the order of ipsilateral replications, ipsilateral grand average, contralateral grand average and contralateral replications. This 2-channel display format facilitates the visual comparison of ipsi and contra waveforms and their trends across levels, usually necessary in order to identify the laterality of response activation (i.e., which is the dominant cochlea) for the specific stimulus.

ABR display example: Normal 500-Hz BC results (20 dB nHL)

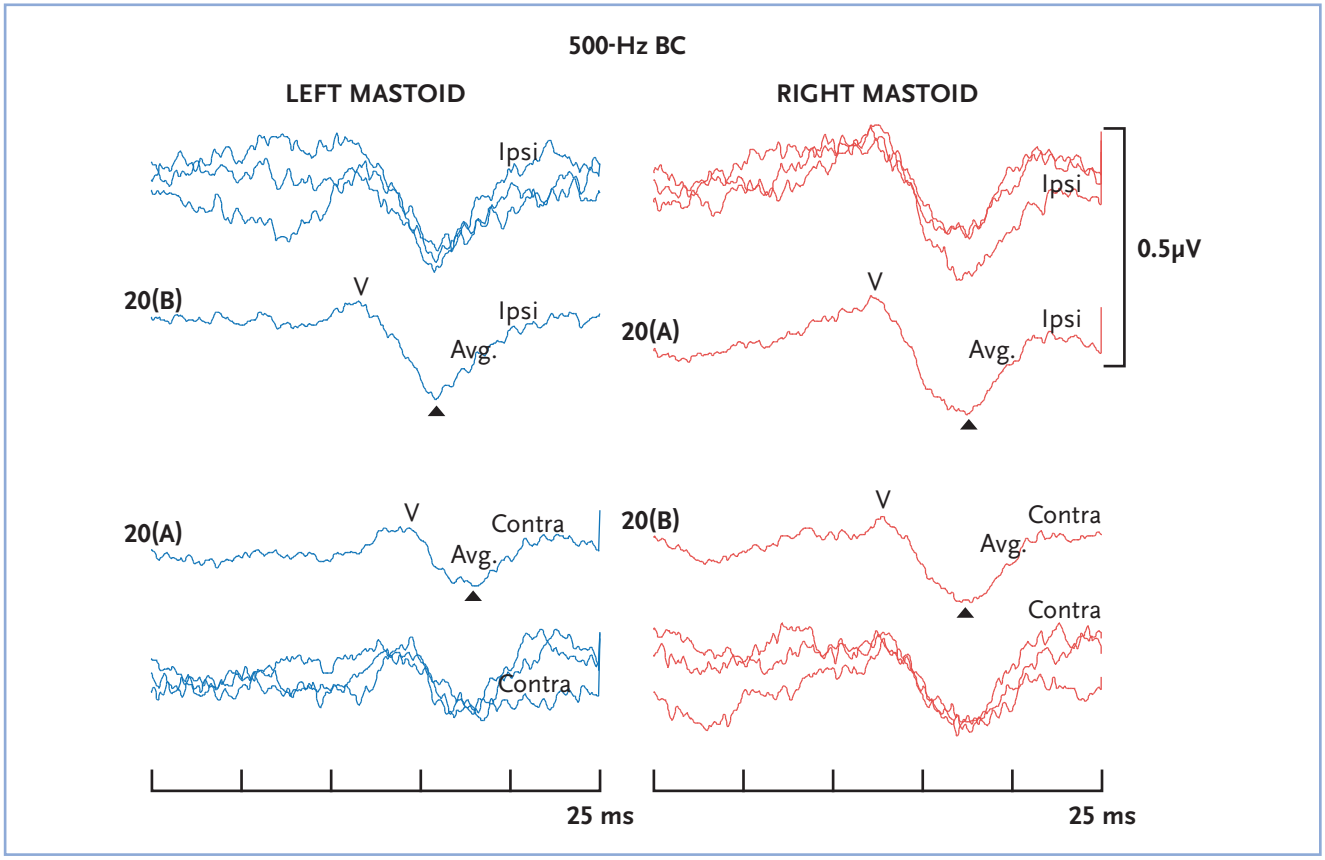


Figure 3.20.3: Example of display of normal 0.5 kHz BC for the left (blue) and right (red) mastoid transducer placement.

ABR display examples: Elevated 2000-Hz BC results (60 dB nHL)

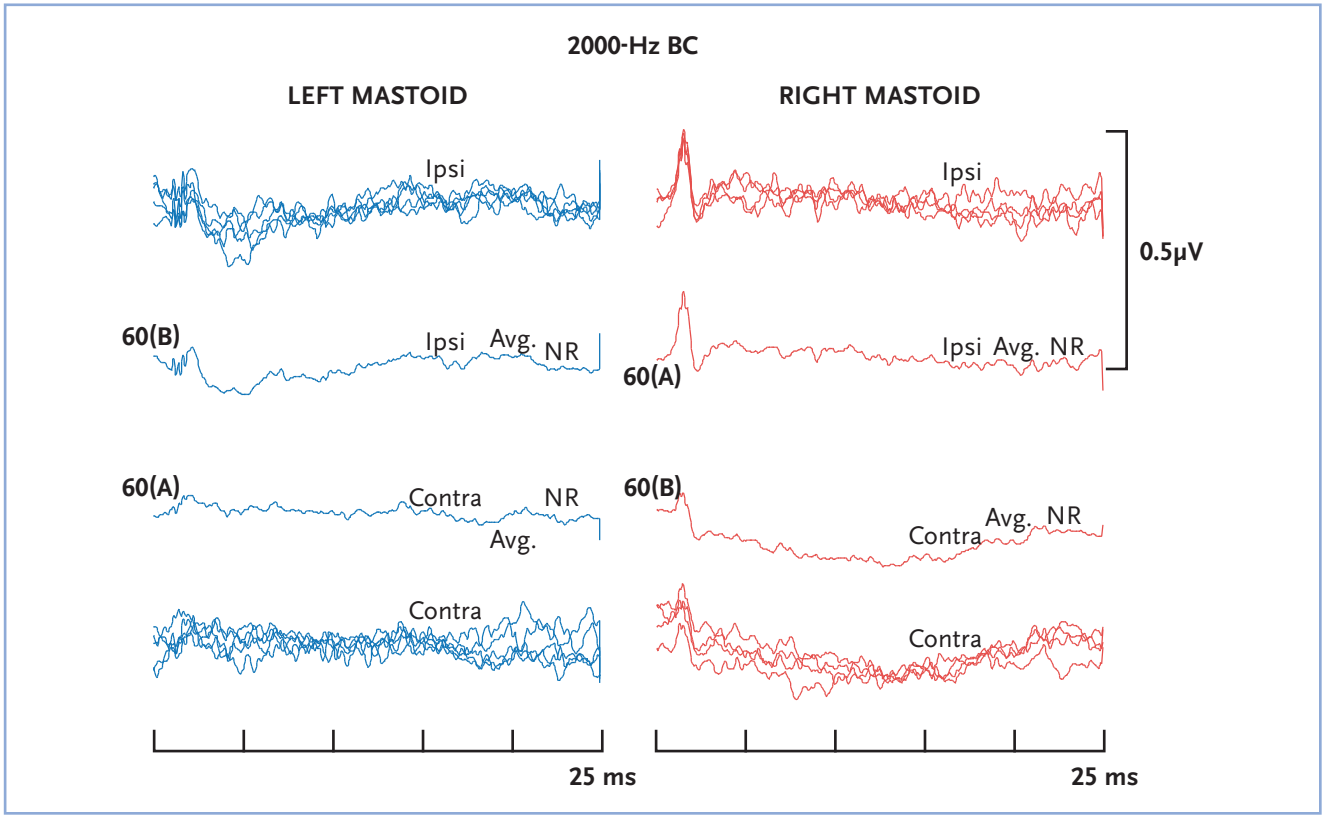


Figure 3.20.4: Example of display of 2-kHz bone-conduction results showing NR in either channel for left (blue) and right (red) mastoid transducer placement. Note the artifactual positive wave in the first 3 ms, seen in both channels, caused by stimulus artifact asymmetry between rarefaction and condensation polarities.

If BC is completed at multiple intensities for the same ear and frequency, it is often easier to keep all the results on one page rather than over multiple pages. Depending on the amount of information, this might mean that results for one ear are displayed over both columns forming a page. In this case, a label at the top of the page should make it clear that the results on the page are from one ear (as opposed to the typical left and right 2-ear display).

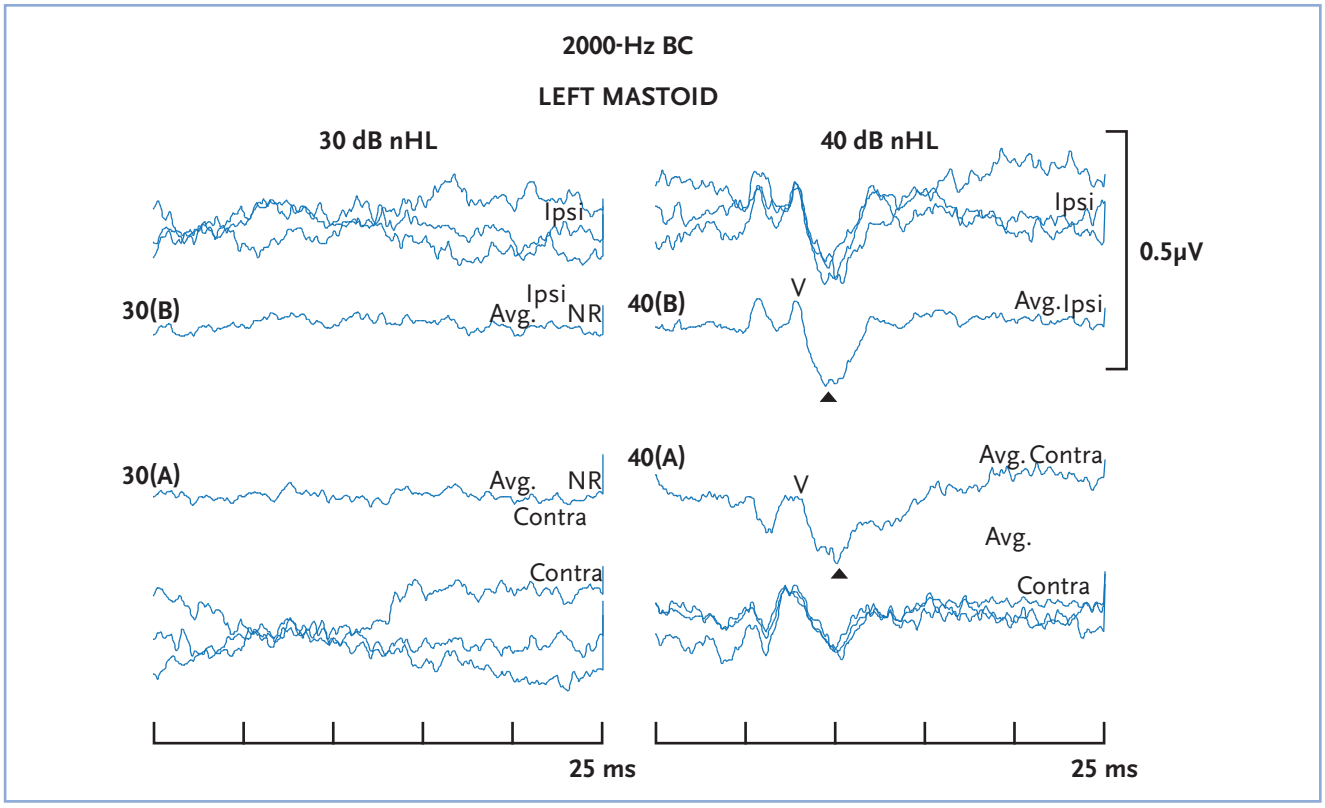


Figure 3.20.5: Display of 2 kHz bone-conduction results at two intensities obtained only for the left mastoid. Results show NR at 30 dB nHL and a clear response at 40 dB nHL with normal ipsi/contra asymmetry (wave V earlier and larger in the ipsilateral channel). Threshold is 40 dB nHL (elevated).

ABR TO CLICKS

When labeling responses to click stimuli, make sure to include the click polarity [rarefaction (RC); condensation (CC)], and at least wave V, and if present wave I (and waves I and V latency and amplitude measures). Labeling of other waves when they are present is optional (e.g., II, III, IV, VI); however, the SmartEP table does not provide any calculations for some of these waves (II, IV, VI).

To calculate the equivalent of a response to "alternating" polarity clicks, average one RC replication with one CC replication. Repeat for each pair of RC and CC replications. (**NOTE:** see Section 5.5 for click display and details on how to calculate the alternating waveform when the number of sweeps differ between RC and CC replications.)

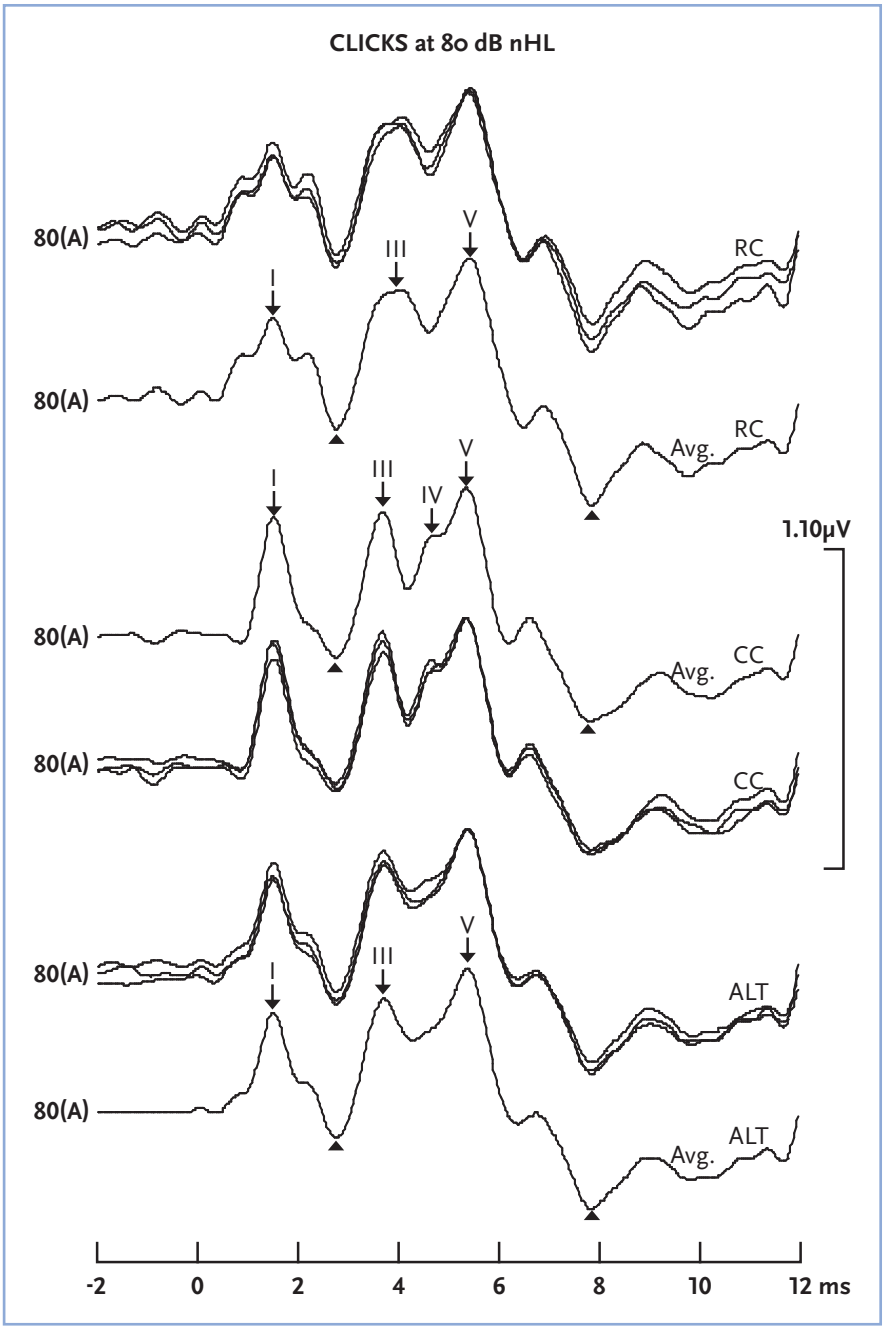


Figure 3.20.6: Example of how to display normal click-ABR results. RC: rarefaction click; CC: condensation click; ALT: alternating polarity (calculated by averaging RC and CC results).

Examples of how to display click-ABR results for children suspected as having ANSD are provided in Section 5.5.

Occasionally, when individual averages are somewhat noisy, superimposition of waveforms can make it difficult to track along each waveform and thus determine reproducibility of a given peak. In such cases, it may help to "pull apart" the waveforms and view them with a slight baseline separation. Displaying the waveforms slightly separated is optional and not normally required. Nevertheless, displaying/printing of all waveforms for a given condition (and electrode, if applicable) *optimally superimposed* (i.e., not "pulled apart") is mandatory. Superimposing waveforms allows for better identification of latency differences in peaks between waveforms, thereby providing better accuracy at identifying peak latencies. If pulled-apart "matched" plotting is also used, it may be printed out alongside the optimally superimposed waves.

4 EFFICIENT PROTOCOLS FOR ABR AUDIOMETRY

4.1 ABR AUDIOMETRY REQUIRES HIGHLY EFFICIENT TEST PROCEDURES

ABR assessments must be efficient. Several techniques are introduced in the following sections, each of which is scientifically valid and proven by experience in early-hearing programs. Examples include: optimizing control of EEG noise, effective and efficient averaging, and stimulus strategies that improve the speed with which crucial clinical information is acquired (e.g., adaptive switching of ear, transducer or frequency; use of large initial intensity step sizes of 30 dB in case of hearing loss).

Babies must sleep for ABR audiometry to be accurate and complete. A substantial amount of information must be obtained in the relatively short time that babies sleep within a test session. Timely and accurate completion of ABR audiometry is thus a challenge. Continuous effort is needed to increase the efficiency of ABR threshold measurement without loss of accuracy and, preferably, with increased accuracy and reduced errors or omissions. One must employ optimal stimulus and recording parameters, which must be combined with accurate response determination, all based on good evidence. These technical procedures are then combined with highly efficient strategic selection and sequencing of stimulus frequencies and routes, as well as to the detailed tactics of intensity selection within individual frequencies and routes of stimulation. The emphasis here is on procedures that will increase the rate of clinical information gained and decrease the rate of significant clinical decision errors or omissions.

A general theme underlying the clinical strategies identified here is to constantly review the specific clinical information that is most important at any point throughout the course of a clinical assessment and to implement the precise procedural step that will yield that information in a valid, accurate and efficient manner. This principle applies to the strategic selection and sequencing of stimulus frequencies and routes, as well as to the detailed tactics of intensity selection within individual frequencies and routes of stimulation.

The following points illustrate some key aspects of more efficient testing that will be explained in more detail in the subsequent sections:

- Throughout threshold estimation, the next stimulus condition chosen should have the greatest impact on clinical management, given what is known at the precise moment of choice.
- For the initial ABR session, start at the minimum stimulus intensity. If NR, switch ears (assuming both ears have insert earphones placed) and test the other ear at the minimum stimulus intensity.
- Go to BC (2 kHz) early when AC at 2 kHz is elevated, to establish hearing loss type right away. This is done *before* determining specific AC thresholds, unless contraindications to perform BC testing are clearly specified.
- When determining threshold, start bracketing initially using large step sizes (30-dB) to quickly obtain a clear response, if present (the morphology and latency may be a useful guide for responses obtained at lower levels).
- Use a strategy of progressive refinement of threshold accuracy. If time allows, 5-dB steps can be used if thresholds are over 70 dB nHL, but not until all 10-dB threshold bracketing as well as other mandatory components are finished.
- In the case where there is a possible response, especially at the normal minimum stimulus intensity, confirm by going up 10 dB. However, except in this case, such small step sizes should not be used for an initial threshold *search* phase.

- Do not allow high-amplitude EEG noise into a good average; use automatic artifact rejection more effectively. In the future, BCEHP *might* use weighted averaging to solve this issue (see Sections 3.9, 3.11 and 3.12).
- The greater the number of sweeps in the average, the less efficient it becomes in terms of information gain per unit test time. Use sweep counts of 1000 to 2000 sweeps per individual average ("replication").
- Proving response absence is often far more time-consuming than proving response presence. Ensure that waveform RN, across all replications, is low enough to determine NR (i.e., RN < 0.08 μV) and the grand-average waveform is visually flat (see Section 3.17).
- For most recordings, one should not need to record more than 3 (sometimes 4) replications per condition to determine RP or NR. *Occasionally,* 5 or 6 replications may be required, but this should be relatively rare. These replications must be combined to obtain an overall grand average for threshold bracketing conditions (lower and upper bounds).
- Routinely recording more than 6 averages per stimulus condition is often inefficient – usually in this case, the infant is not quietly asleep. Attempts to quiet the infant are recommended and should be done before going up in intensity (by 10 or 20 dB) to find possible responses above the large EEG noise. The challenge in such cases is that real responses might be present at lower intensities but do not meet noise criteria and thus are deemed as CNE. Obtaining CNE results at the lower intensities provides no clinical information and should therefore be avoided as much as possible.

4.2 OPTIMIZING CLINICAL INFORMATION GAIN

In contrast to behavioural audiometry in a cooperative adult, high-quality infant ABR audiometry must be conducted so that every choice made for the next stimulus condition is the one that would yield the greatest net clinical impact if the test were to be terminated immediately thereafter. Switching ears early (and often) and going to BC early improve clinical efficiency.

ABR threshold measurements must be done with the highest possible clinical efficiency, always being cognizant that testing might be terminated at any time with no further testing possible (e.g., the baby wakes up). Further, attendance for additional ABR sessions may be difficult to arrange. Thus, each and every choice of next stimulus condition must be such that clinical management will depend strongly on the answers obtained for the chosen condition.

Common situations that *limit the efficiency* of ABR audiometry are:

- getting bogged down in threshold *accuracy* before answering bigger clinical questions (such as "Is hearing loss present in one or both ears?" or "Is hearing loss sensorineural or conductive?")
- not switching ears early (or often) enough in the testing session
- not doing BC early enough
- using ascending step sizes that are too small (e.g., 10 dB), losing time getting to threshold bracketing regions
- lengthy or repeated averaging when a possible response is highly questionable (i.e., chasing shadows), rather than going higher to get a clear response to guide decisions at lower intensities
- testing discretional conditions before obtaining clear results for all mandatory components

The general strategy of successful ABR audiometry in infants is the opposite of behavioural audiometry in a co-operative adult subject, which typically proceeds by stepping through a standard testing sequence from beginning to end. In an infant, ABR testing may be permanently terminated at any moment, perhaps after the very next average. This means that *the next stimulus condition (delivery (AC/BC) frequency, intensity...) must be the one that will make the biggest difference to clinical decisions and management,* of all the stimulus choices available. If this strategy were followed continuously, then no matter when the session ends, it would not have been possible in retrospect to have obtained any more valuable clinical information in the time that turned out to be available.

Pressure related to time is constant in infant ABR audiometry, especially when testing an infant with hearing loss. It is a difficult task to achieve consistently accurate and complete initial ABR audiometry followed by appropriate intervention within the timelines established as international benchmarks. There is rarely any time to waste taking measurements that are not clinically important. Moreover, it is quite common across most EHDI programs that many assessments are incomplete, uncertain or not timely. The need for a top-down approach with progressive refinement of information obtained cannot be overstated. It is important that the ABR Audiologist approach each ABR test session, *especially the initial-ABR session*, with an open mind as to possible results, rather than having a preconceived idea or hope as to what the results will be.

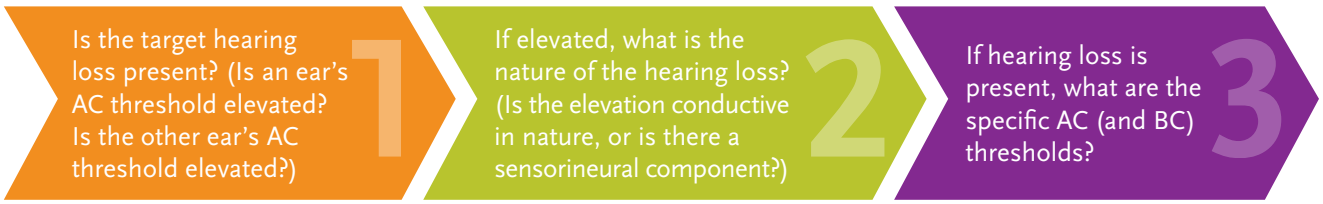
4.3 STRATEGY OF STIMULUS FREQUENCY AND ROUTE

For most initial ABR tests in infants, the optimal test strategy requires adaptive switching between test ears, switching between stimulus delivery methods (AC and BC) and switching of stimulus frequencies. In general, initial ABR audiometry for most infants aims to answer the following three questions for each ear, in order of priority: (1) **Is the target hearing loss present?** (Is an ear's AC threshold elevated? Is the other ear's AC threshold elevated?); (2) **If elevated, what is the nature of the hearing loss?** (Is the elevation conductive in nature, or is there a sensorineural component?); and (3) **If hearing loss is present, what are the specific AC (and BC) thresholds?**

ABR audiometry requires testing of both ears, regardless of hearing screening results. Testing is considered incomplete until both ears are done; if incomplete, a second appointment is required. As both ears must be tested, the choice of which ear to test first is often determined by infant sleeping position and ease of access to ears. In the case of a unilateral hearing screening fail, clinicians may, discretionally, decide to start testing with the ear that failed the screening.

For most initial ABR tests, the optimal test strategy requires adaptive *switching between test ears, switching between stimulus delivery methods (AC and BC) and switching of stimulus frequencies*. Switching ears is usually possible as insert earphones should be placed in *both* ears prior to the start of testing. Switching to BC testing is fairly easy, and insert transducers do not need to be removed for BC testing (infants < 12 months of age).

In general, initial ABR audiometry for most infants aims to answer the following three questions, **in order of priority:**



The first question, **"Is the target hearing loss present?"**, is answered by testing each ear at a minimum stimulus intensity that identifies whether or not a hearing loss is present for that frequency. Most babies referred from screening for ABR audiometry will have normal or near-normal hearing. Initial ABR testing for these cases would thus not routinely require a detailed threshold search. If the baby wakes up at the end of this, the ABR Audiologist is able to state whether one or both ears' thresholds are elevated. In the range of 0.5 to 4 kHz, the most valuable of all single answers in relation to early language development and the epidemiology of hearing loss in newborns is at 2 kHz. It follows that the initial starting condition should be AC 2 kHz at the minimum stimulus intensity. Starting with a higher intensity at 2 kHz is inefficient because (i) obtaining a clear response at a higher level cannot rule out hearing loss, and (ii) in infants with normal hearing, a clear ABR will usually be obtained at the minimum stimulus intensity.

If responses are present for both ears at the AC 2 kHz minimum stimulus intensity, then testing proceeds to other frequencies at their minimum stimulus intensities.

If either (or both) ear shows NR at the AC 2 kHz minimum stimulus intensity, the next important question is **"If elevated, what is the nature of the hearing loss?"** This second question is answered by BC testing of the ear(s) with AC elevation, with BC testing starting at the minimum BC stimulus intensity. If the infant wakes up at the end of this stage, the ABR Audiologist is able to state that the elevation in AC threshold is conductive or sensorineural in nature. As the majority of infants with elevated AC thresholds will turn out to have conductive losses, this procedure will most often quickly identify an infant's elevation as conductive in nature, providing important information for subsequent management and for the infant's caregivers.

If the AC elevation proves to be conductive and is presumed to be temporary in nature, the specific level of the AC threshold may be less useful if it is a "moving target" (i.e., fluctuating between test sessions). Appropriate management of the hearing loss and providing information to parents are important and depend upon knowing the nature of the loss. Hence, during the initial ABR audiometry session, when an AC elevation is present, BC testing becomes a higher priority than determining the AC threshold. *Going early to BC testing (i.e., once an AC elevation has been confirmed) is thus a priority for ABR audiometry.* Demonstrating a reasonable range of AC thresholds is required by BCEHP for complete ABR audiometry when temporary CHL is suspected.

In the rare cases where switching to BC testing proves difficult, an efficient alternative when there is NR at the AC 2 kHz minimum stimulus intensity (30 dB nHL) is to immediately go up 30-dB higher. Getting a positive response quickly at about 60 dB nHL is much more informative than getting an inconclusive or negative result having gone up by only 10 dB, for example. In addition, getting NR at 60 dB nHL has major clinical impact, is much more informative than getting NR at 40 dB nHL and avoids wasting time chasing borderline responses.

If a NR was obtained at AC 60 dB nHL, is it better to go to 80 dB nHL or to BC? You know that there is a substantial hearing loss, so its permanence has become crucial. This argues for switching to BC.

When going to BC, a question is whether to start at the BC 2 kHz minimum stimulus intensity or a higher intensity, given NR for AC at 30 and/or 60 dB nHL. The *minimum stimulus intensity has priority* because the ability to state that BC is normal has major clinical impact.

After it has been determined that there is a hearing loss present (by testing both ears at AC 2 kHz minimum stimulus intensity) and whether the elevation is conductive or sensorineural in nature (by testing BC), the third question, "**If hearing loss is present, what are the specific AC (and BC) thresholds?"**, is answered by obtaining detailed threshold information for AC stimuli at 2, 0.5 and 4 kHz (and, when specified by these protocols, at 1 kHz), as well as BC thresholds at 2 and 0.5 kHz, where specified.

The above does not indicate the exact priority sequence of testing for stimulus frequencies. In general, greatest priority is given to 2 kHz, and results for this frequency are usually obtained first. Next tested is usually 0.5 kHz, as this can be tested using both AC and BC stimuli. However, ABR results for 4 kHz stimuli are usually easy to recognize and thus very quickly obtained (especially compared to 0.5 kHz). Thus, AC 4 kHz *may* be tested before 0.5 kHz *when AC 2 kHz is normal.* If AC 2 kHz threshold is elevated, then 0.5 kHz must be tested before 4 kHz. Section 4.14 provides some typical test sequences.

The relative clinical importance of a given stimulus condition changes as the answers are obtained from other stimulus conditions, so the whole process of choosing the most influential next stimulus condition is dynamic and constantly evolving as the assessment proceeds. The sequence outlined above, as determined by the above questions to be answered, will be appropriate for most infants requiring ABR audiometry.

Typical and Efficient Tone-ABR Test Sequence

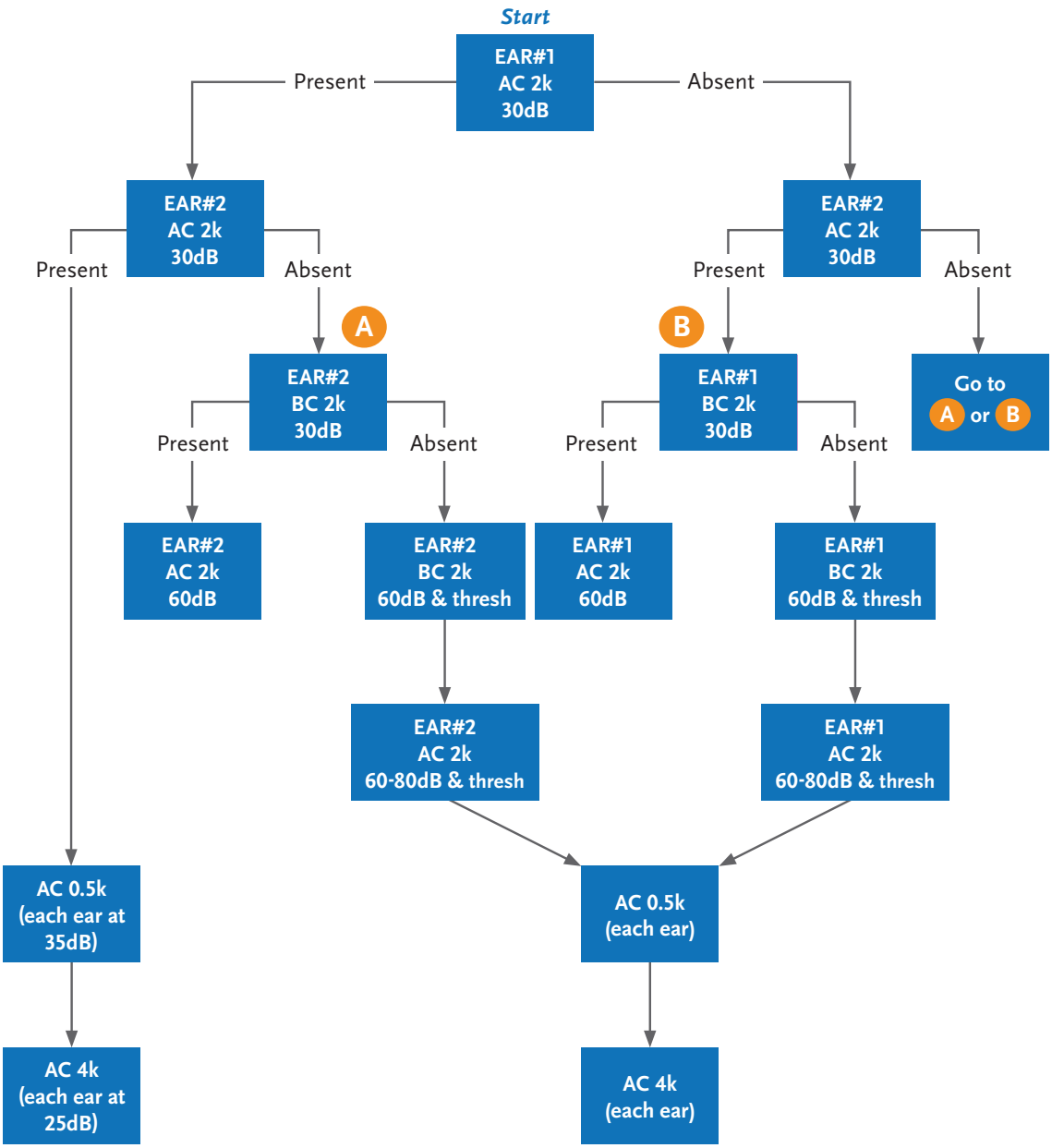


Figure 4.3.1: shows a flowchart typical of an efficient tone-ABR test sequence used by BCEHP ABR Audiologists. (Adapted from Stapells, 2002.)

4.4 MANDATORY AND DISCRETIONAL PROCEDURES FOR DETERMINING HEARING STATUS

This section contains a summary of important test components for initial ABR audiometry. The tests are grouped according to hearing type and as procedures that must always be done (Mandatory), procedures that may be done under certain circumstances (Conditional Mandatory) and those that may be done if the ABR Audiologist chooses (Discretional).

Mandatory elements are always completed except under exceptional circumstances. When mandatory elements are not fulfilled, a brief explanation is entered in the clinical record. Exceptions are evaluated as part of the ABR CQI process. Print/electronic copies/PDFs must be available for all test procedures completed. Cursory Otoscopy is always mandatory.

Note that while the mandatory procedures in this section satisfy the minimum information needed for each type of hearing outcome, further testing beyond the mandatory minimum is often possible within a test session and often provides valuable clinical information.

Normal Hearing	
Mandatory Procedures	AC-ABR testing at 2 kHz (response at 30 dB nHL) both ears, 0.5 kHz (response at 35 dB nHL) both ears, 4 kHz AC (response at 25 dB nHL) both ears
Discretional Procedures (these measures are recommended if time permits because they are helpful as a cross check to the ABR results and for maintaining skills)	AC-ABR testing at 1 kHz (response at 35 dB nHL) both ears Tympanometry: (i) younger than 6 months corrected age: probe tone of 1 kHz; (ii) age 6 months or older: probe tone of 226 Hz DPOAE amplitude and noise measurements at 2, 3 and 4 kHz nominal f2

Presumed Temporary Conductive Hearing Loss	
Mandatory Procedures	Elevated AC ABR showing a threshold range at 2 kHz (or 0.5 kHz if it is the only AC threshold elevation) with normal BC at the corresponding frequency. For example, showing a range between 40-70 dB nHL is often sufficiently informative. Note that BC 0.5 kHz is only required if 0.5 kHz AC is the only elevation. Tympanometry: (i) younger than 6 months corrected age: probe tone of 1 kHz; (ii) age 6 months or older: probe tone of 226 Hz
Discretional Procedures	BC-ABR testing at 0.5 kHz and 4 kHz at the normal minimum intensity 10-dB final threshold bracketing for AC ABR at 2 kHz, 0.5 kHz, and 4 kHz (i.e., minimum requirement for purely conductive loss that is suspected to be transient in nature is demonstration of a reasonable range of AC threshold at one frequency with normal BC at the corresponding frequency). If AC elevation (at 0.5 kHz and/or 2 kHz) is only 10 dB nHL above the normal minimum intensity and BC ABR is present at the normal minimum intensity, additional BC testing at 10 dB below the normal minimum intensity should be considered in order to confirm conductive component (see Section 4.13). DPOAE amplitude and noise measurements at 2, 3 and 4 kHz nominal f2 4-kHz AC and 1-kHz AC are not required

Microtia/Atresia: For ear(s) where insert earphone/probe placement is not possible	
Mandatory Procedures	Elevated AC ABR (TDH headphones) showing a threshold range at 2 kHz (e.g., showing a range between 40-70 dB nHL is often sufficiently informative). In the rare case that 2 kHz is normal, test 0.5 kHz. BC-ABR testing at 2 kHz and 0.5 kHz. Note that both BC 0.5 kHz and 2 kHz are required because amplification options are limited to BC devices.
Discretional Procedures	BC-ABR testing at 4 kHz 10-dB final threshold bracketing for AC ABR at 2 kHz, 0.5 kHz, and 4 kHz

Permanent Hearing Loss (includes Sensorineural, Mixed & Permanent Conductive)	
Mandatory Procedures	AC-ABR testing at 2 kHz, 0.5 kHz and 4 kHz, with 10-dB final threshold bracketing BC-ABR testing at 2 kHz if AC 2 kHz threshold is elevated; 10-dB final threshold bracketing when BC shows a NR at the minimal stimulus intensity (up to and including NR at 60 dB nHL) Tympanometry: (i) younger than 6 months corrected age: probe tone of 1 kHz; (ii) age 6 months or older: probe tone of 226 Hz DPOAE amplitude and noise measurements at 2, 3 and 4 kHz nominal f2
Conditional Mandatory Procedures	BC-ABR testing at 0.5 kHz *if AC 0.5 kHz threshold is the only elevation*; 10-dB final threshold bracketing when BC is absent at the minimal stimulus intensity (up to and including NR at 50 dB nHL) AC-ABR testing at 1 kHz (10-dB bracketing, if elevated), *if the difference (in dB nHL) between AC 2 kHz and AC 0.5 kHz exceeds 20 dB* AC 2 kHz at 20 dB nHL *if AC 4 kHz threshold is the only elevation* (this is an exception to the minimum stimulus intensity rule) AC Clicks *if AC ABR at 2 kHz has a severely delayed or absent wave V ≥ 80 dB nHL* (see ANSD subprotocol for details about clicks) *If unilateral/asymmetric hearing loss, 2-channel AC recordings* must be obtained to allow comparison of ipsilateral and contralateral asymmetries in order to determine responding ear. A clinician should switch to 2-channel AC viewing when responses in one ear are at the normal minimum intensity and the other ear thresholds are greater than or equal to 60 dB nHL, or (ii) thresholds are elevated in both ears with at least a 40-dB threshold difference (in dB nHL) between ears.
Discretional Procedures	The application of contralateral masking is always discretional. However, if AC/BC 2-channel ipsi/contra asymmetries are unclear or abnormal, application of contralateral masking may be necessary to determine responding ear. BC 4 kHz (especially if AC 4 kHz is the only threshold elevation) If AC-ABR thresholds are greater than 70 dB nHL, 5-dB AC threshold bracketing may be pursued, but only after all mandatory measurements are completed Ipsilateral acoustic reflexes (broadband noise or 1 kHz) Real-ear-to-coupler difference determination, where non-ANSD PHL is confirmed

ANSD or Retrocochlear Disorders: Subprotocol Required	
In addition to the requirements specified for permanent hearing loss (above), if there is no clear tone-ABR wave V-V' for any 2 kHz intensity tested ≥ 80 dB nHL, the subprotocol for ANSD or retrocochlear disorders should be initiated (after all tone-ABR has been completed).	
Mandatory Procedures	Slow-rate (19.1-21.1/s), separate recordings of RC and CC at 90 dB nHL (at least 2 replications for each polarity), for assessment of cochlear microphonic potentials (CM), cochlear summating potentials (SP) and neural components (ABR waves I to V presence, morphology, latency, amplitude). No-stimulus recordings to either RC or CC by clamping insert earphone tube (if clamp tube recording is not clearly flat in the first 0-3ms post-stimulus, then testing of both polarities is required). Determination of ANSD requires low-noise recordings, as responses with low peak-to-peak amplitudes are often assessed. When **both** CM and wave V amplitudes are very small (< 0.1 μV p-p), the SmartEP RN amplitude must be no more than 50% of the CM and wave V peak-to-peak amplitudes. If not, additional trials/replications should be obtained to reduce the waveform RN (with RN=0.04 μV being the practical limit; i.e., no need to try to get RN lower than 0.04 μV). Specific analyses are required for the above data: (i) RC and CC grand averages, (ii) the alternating polarity replications and their grand average (calculated by averaging sets of RC and CC averages), (iii) RC grand average and the CC grand average butterfly plot, (iv) either the RC-CC or CC-RC subtraction (from the RC and CC grand averages), and (v) grand average of the RC or CC clamped-tube no-sound condition.
Conditional Mandatory Procedures	If cochlear (CM and/or SP) potentials cannot be differentiated from wave I, then separate recordings using a very fast rate (91.1-101.3/s) of RC and CC at 90 dB nHL (at least 2 replications for each polarity), are required to help tease out cochlear from neural responses. For example, stimulating at this fast rate will often substantially reduce or remove neural potentials (especially wave I), but not the CM or summating potential, SP (both cochlear potentials). For unilateral hearing loss, 2-channel recordings are required. Masking may also be helpful. See Section 4.11 for when to use 2-channel recordings (and possibly masking).
Discretional Procedures	Click-ABR *threshold*, as part of the ANSD subprotocol. In very rare cases, the tone-ABR protocol may miss an island of better hearing that the broadband click-ABR reveals (i.e., NR to tones but clear wave V to clicks). Acoustic reflex measurements: They have some value as a crosscheck when ABRs are absent at high stimulus levels, in that reflex presence contradicts inference of both ANSD and profound conventional cochlear hearing loss. In general, reflex presence may be clinically informative, whereas reflex absence is rarely so. Acoustic reflex measures should only be obtained after all mandatory components have been completed.

Detailed information regarding ABR testing for ANSD are provided in Section 5.

See ABR Audiometry Quick Reference Guide for a short-form summary of mandatory, conditional mandatory and discretion procedures.

4.5 TONE-ABR THRESHOLD DEFINITION

Threshold is defined by the lowest RP and NR pair of stimulus intensities (in dB nHL), separated by 10 dB or less. The upper RP level defines threshold in dB nHL. If the difference between the lowest RP level and the highest NR is greater than 10 dB, then "threshold" is defined as a range: (NR+10dB) level in dB nHL to RP level (e.g., 30-40 dB nHL). Sometimes a threshold has not been bracketed: for example, if a RP is found but without verification of a NR at a lower level, then the threshold must be reported as being less than or equal to (≤) the RP level. Or, if NR is obtained at any level and a RP is not verified, threshold must be defined as being greater than (>) the NR level.

In practice, ABR threshold is defined using the wave V-V' downslope as the key feature, because V-V' is usually the most detectable peak-to-trough component of the ABR waveform at stimulus levels near threshold. For any given stimulus route (AC or BC) and frequency, there are three common overall outcomes from any given ABR audiometry assessment:

- An ABR threshold is considered bracketed if there are two stimulus levels separated by no more than 10 dB, with the lower level having NR and the higher level having a RP.
- There is NR at the highest level tested, which defines a lower bound for the unknown threshold (threshold > highest level tested), or
- There is a response at the lowest level tested, which yields an upper bound for the threshold (i.e., threshold ≤ lowest level tested).

Both the levels and the threshold bracket or boundary decisions must be documented on the ABR waveforms and in the clinical report. This greatly facilitates understanding of clinical findings by others, retrospective review or evaluation of threshold estimates, and is of particular value in serial testing or in cases of unexpected change or discrepancies across measurements.

If earlier waves (e.g., I or III) are clearly present but V-V' is not, then an ABR threshold cannot be defined in conventional terms because historically, most normative ABR threshold data are based on wave V. Moreover, absence of V-V' with present wave I implies retrocochlear disorder, for which ABR threshold inferences are inherently questionable. Earlier waves must be confirmed as biological in nature by performing a clamped tube recording whereby they disappear. If these early waves remain, then they are stimulus artifact. *Presence of earlier biologic waves indicates a response by the cochlea to the stimuli, and this finding should be clearly reported.*

4.6 TONE-ABR THRESHOLD SEARCH AND BRACKET PHASES

In general, for each AC tone threshold frequency, there is a **"search"** phase that gets to the threshold region as quickly as possible and a **"bracket"** phase that focuses on accuracy of response decisions. For the initial ABR at least, when threshold is elevated, the bracket phase usually occurs after switching testing to the other ear as well as some BC testing.

The search phase for any given AC frequency and ear with NR at the normal minimum stimulus intensity (i.e., threshold is elevated) ascends in large steps (up 30 dB, then 20-30dB steps) to find a RP judgment quickly. The ABR Audiologist uses this RP's morphology (how large and sharp) and latency as a detection guide for recordings for this ear and frequency at any lower levels. Descent-step size after a 30-dB ascent may be varied, taking into account the size and clarity of any RP result. Search phase ascent in 10-dB steps

(or, worse still, 5-dB steps) is usually extremely inefficient and is strongly discouraged unless there is a very strong clinical rationale (e.g., to confirm a questionable but suspected RP). The bracket phase is entered in order to determine response threshold with 10-dB accuracy (i.e., no more than a 10-dB difference between the lowest RP and highest NR). For the initial ABR at least, when threshold is elevated, the bracket phase usually occurs after switching testing to the other ear as well as some BC testing.

The ABR audiometry protocol does NOT involve routine use of an "intensity-latency" (or intensity-amplitude) input-output function approach to estimate threshold because there is evidence of insufficient accuracy and reliability (e.g., Birkent et al., 2017; Chisin et al., 1983; Mackersie & Stapells, 1994; Oates & Stapells, 1992; reviewed in Small & Stapells, 2017). Therefore, the general idea of obtaining an "intensity series" with small step size (e.g., every 10 dB) is highly discouraged.

4.7 TONE-ABR THRESHOLD BRACKET STEP SIZE

The target threshold bracket width is 10 dB. Brackets of 5 dB are discretional, and should only be done after all mandatory thresholds bilaterally are completed to their 10-dB brackets.

For ABR audiometry to be considered complete, the final threshold bracket step size for all required AC frequencies must be no greater than 10 dB. If the ABR threshold estimate with that bracket is greater than 70 dB nHL, a 5-dB step size may be used for the final bracket. The increased precision may be relevant to accurate prescription of amplification, if the residual dynamic range is very limited. However, frequently it is challenging to make clear RP and NR decisions with steps of only 5 dB, which uses valuable test time for little clinical benefit; if the threshold is below 70 dB nHL, the clinical benefit is negligible. *Therefore, brackets of 5 dB are discretional and must only be done after all mandatory thresholds are completed bilaterally to their 10-dB brackets. BCEHP does not use a 5-dB step size for BC recordings.*

4.8 CONFIRMATION OF UPPER BRACKET RESPONSE

Occasionally, if there is any doubt about the upper bracket RP, go up 10-20 dB for one replication, for rapid response confirmation and waveform morphology and latency guidance.

If averages show a clear replicable response with expected morphology, and if the grand average SNR is greater than 1.0, then there is little doubt it is an RP. Occasionally, if there is any doubt about the upper bracket RP after 2-6 replications, go up 10-20 dB for one replication, for rapid response confirmation and waveform morphology and latency guidance, rather than simply doing several more replications at the questionable bracket level. Response presence must be verified at the confirmation level in order to accept the threshold bracket as valid. In most cases, however, the upper bracket response will be clear and not require confirmation at a higher intensity.

4.9 DETERMINING THE RESPONDING COCHLEA: IPSILATERAL/ CONTRALATERAL ASYMMETRIES

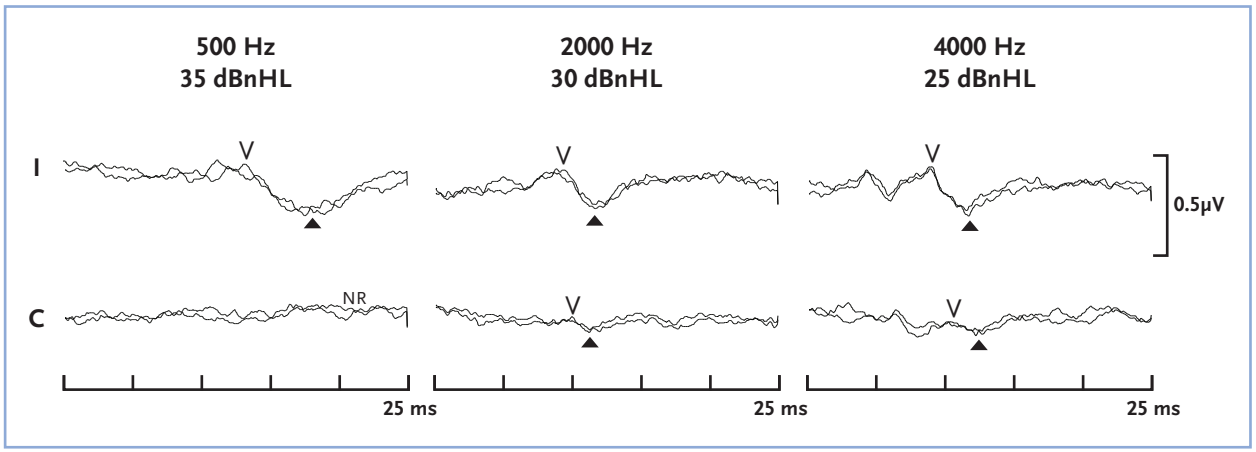
When the possibility of acoustic crossover exists – BC at all intensities and AC at high intensities when inter-ear threshold asymmetry exists – the responding cochlea for BC and AC measurements will be determined by evaluation of the response amplitude and latency differences in the EEG channels ipsilateral and contralateral to the AC/BC transducer placement. Reliably present in infants and young children in response to both AC and BC stimuli, the wave V-V' complex is larger and earlier in the channel ipsilateral to the cochlea that is being excited more effectively by the stimulus. In most cases, these ipsi/contra asymmetries may be used to infer which cochlea is responding to the stimuli in infants.

Each ear with AC-ABR elevation must be stimulated individually with the BC transducer placed high on the ipsilateral mastoid. For all BC testing, and for AC testing when significant inter-ear asymmetry exists (see Section 4.11), two forehead-mastoid EEG recording channels (Fz-M1 and Fz-M2) must be used. The responding cochlea ("response laterality") for BC (and some AC) measurements will be determined by evaluation of the wave V-V' response amplitude and wave V latency differences in the EEG channels ipsilateral and contralateral to the AC/BC transducer placement.

In an infant with normal hearing, the contralateral ("contra") recording channel (i.e., Fz to mastoid contralateral to stimulus transducer placement) to AC and BC stimuli shows a wave V response that is much smaller in amplitude and later in latency compared to the ipsilateral (ipsi) recording channel (Edwards et al., 1985; Stapells & Mosseri, 1992; Stapells & Ruben, 1989). In very young infants, in addition to being smaller, the waveform in the contra channel sometimes appears "inverted" compared to the ipsi channel (Edwards et al., 1985; Stapells & Mosseri, 1992). This contrasts with results in older children and adults, where the ABRs in the ipsi and contra channels look very similar, except for wave I (which is absent in the contra channel for all ages) (Edwards et al., 1985; Stapells & Mosseri, 1992; Foxe & Stapells, 1993). As shown in Figure 4.9.1., these infant ipsi/contra differences (asymmetries) are seen in response to AC and BC tonal stimuli.

First reported by Stapells and colleagues (Gravel et al., 1989; Stapells, 1989; Stapells & Ruben, 1989; Foxe & Stapells, 1993; for review, see Small & Stapells 2017), the responding cochlea in young infants can usually be identified by comparing the ipsilateral and contralateral averages to AC and BC stimuli. They are particularly useful for determining response origin ("laterality") for BC stimuli. In infants and especially near-threshold levels, the V-V' complex is usually larger and wave V latency is usually earlier in the channel ipsilateral to the cochlea that is being excited more effectively by the BC (or AC) stimulus. Although historically BCEHP has placed more weight on ABR latencies, it now places equal emphasis on amplitude and latency measures when interpreting ipsilateral/contralateral differences. These ipsi/contra asymmetries are reliably present in infants and even young children in response to both AC and BC stimuli and may be used to infer which cochlea is responding to the stimuli (Stapells & Ruben, 1989; Stapells & Mosseri, 1991).

A: Responses to AC tones



B: Responses to BC tones

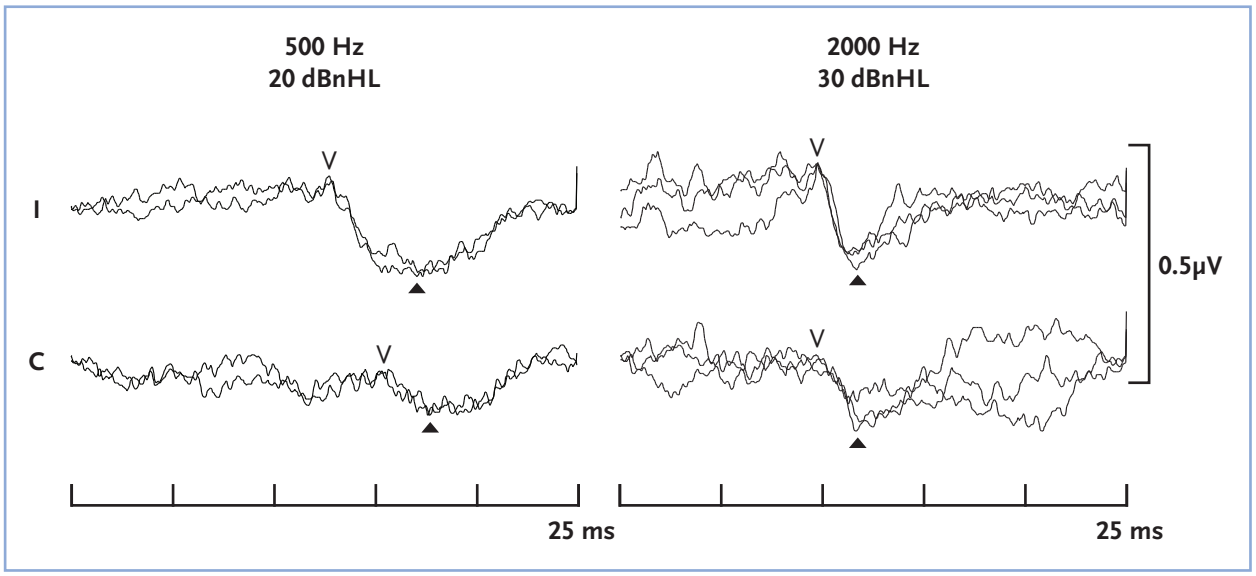


Figure 4.9.1: Normal infant ipsilateral/contralateral EEG channel asymmetries in response to AC and BC tones at normal minimum stimulus intensities, with larger V-V' amplitude and earlier wave V latency in the ipsilateral compared to contralateral channels. These indicate that the ipsilateral cochlea is responding. A: Responses to AC tones; B: Responses to BC tones.

The mechanisms underlying wave V-V' ipsi-contra asymmetries in children is not fully understood, but it is likely due, at least in part, to orientation of neural generators changing with maturation, and possibly delayed maturation of contralateral pathways. Nevertheless, over 30 years experience with such measurements indicates the inference is generally valid (Small & Stapells, 2017; Stapells, 1989; Stapells & Ruben, 1989).

In contrast to adult testing, in the infant, intra-cranial transmission losses for BC stimuli are sufficiently large that *each ear must be tested individually*; that is, it should not be assumed that a given mastoid placement stimulates both cochleae equally. For BC-ABR testing in infants, transcranial sound transmission losses can vary across infants from about 5 to 30 dB. Infants aged less than 12 months show *at least* 10-dB interaural attenuation (Mackey et al., 2018; Yang & Stuart, 1990). The exact mechanism of these differences may be dynamically very complex, but the net effect appears to be that the bony plates of the skull are less strongly coupled in infants, to varying degree.

As noted above, ipsi/contra asymmetries in adults and older children are very small, sometimes absent, and not a reliable indicator of response origin. In infants with hearing loss (and very occasionally in infants with normal hearing), ipsi/contra latencies and amplitudes do not always conclusively indicate response laterality. Latency and amplitudes across channels may even be in apparent conflict (e.g., shorter latency in the ipsilateral channel but larger amplitude in the contralateral channel, or vice versa). Figure 4.9.2 describes likely patterns and how they are interpreted. In these cases, it is important that wave identification and measures are confident and recordings have very low noise. Additional testing at other intensities may help determine which cochlea is responding. Often, however, masking of the contralateral cochlea is required when ipsi/contra asymmetries do not provide conclusive results about laterality.

It is important to differentiate ipsi/contra EEG recording channels from ipsi/contra ear/cochlea. The ipsi and contra recording channels refer to the relationship of the recording channel to transducer placement; the ipsi channel is that channel which is on the same side as placement of the earphone or bone oscillator. The contra channel is on the opposite side from the transducer. The ipsi/contra channel designation, by itself, does **not** indicate the cochlear origin. Indeed, a response may be seen in both the ipsi and contra EEG channel in conditions where only the cochlea on the same side as the transducer was stimulated and no acoustic crossover exists (e.g., low-intensity AC stimuli, Figure 4.9.1a). However, in the case of acoustic crossover that stimulates the cochlea on the opposite side – such as with BC stimuli – the contra EEG channel may include contributions from both the ipsi and contra cochleas (assuming the stimulus is above threshold). Further, in this example, the ipsi EEG channel will contain contributions from both the ipsi and contra cochleae. It is the ipsi/contra EEG channel amplitude and latency differences (asymmetries) that we use to indicate which cochlea (or cochleae) have contributed to the responses.

Figure 4.9.2 demonstrates how BCEHP currently interprets infant BC- and AC-ABR ipsilateral/contralateral EEG channel asymmetries, *especially when tested at the normal minimum stimulus intensities (for BC)*.

In the simplest example, if the ipsi channel shows a clear ABR wave V-V' and the contra channel shows NR (A in Figure 4.9.2), this indicates the ipsilateral cochlea (i.e., on the same side as the transducer placement) is responding. Another "simple" example is shown in D, when NR is seen in either channel and thus the ipsilateral cochlea has not responded. Note, however, that neither pattern (A or D) provides any information about the contralateral cochlea.

More typically, however, there is a response seen in both channels; wave V latencies and amplitudes across channels are thus compared. Example B is the typical normal result (also shown in Figure 4.9.2), with both wave V latency earlier *and* V-V' amplitude larger in the ipsilateral channel, indicating that the ipsilateral cochlea is responding. Example C is a little more complicated but is interpreted the same as B, with similar latencies but larger ipsilateral amplitude. To reiterate, examples A, B and C are considered "normal" asymmetries and indicate that the ipsilateral cochlea responded, regardless of the stimulus intensity.

Infant ABR ipsilateral/contralateral asymmetries are more complicated when there is a sensorineural component in the ipsilateral cochlea with better sensitivity in the contralateral cochlea, especially for responses to BC stimuli. Example E shows the simplest example of this: NR is seen in the ipsilateral channel whereas the contralateral channel shows a clear response. At all stimulus intensities, this pattern indicates NR from the ipsilateral cochlea and that this response is the result of crossover to the contralateral cochlea. When testing at the normal minimum intensity, pattern E indicates a sensorineural component in the ipsilateral cochlea and likely normal cochlear sensitivity in the contralateral cochlea; however, the contralateral cochlea should be tested directly.

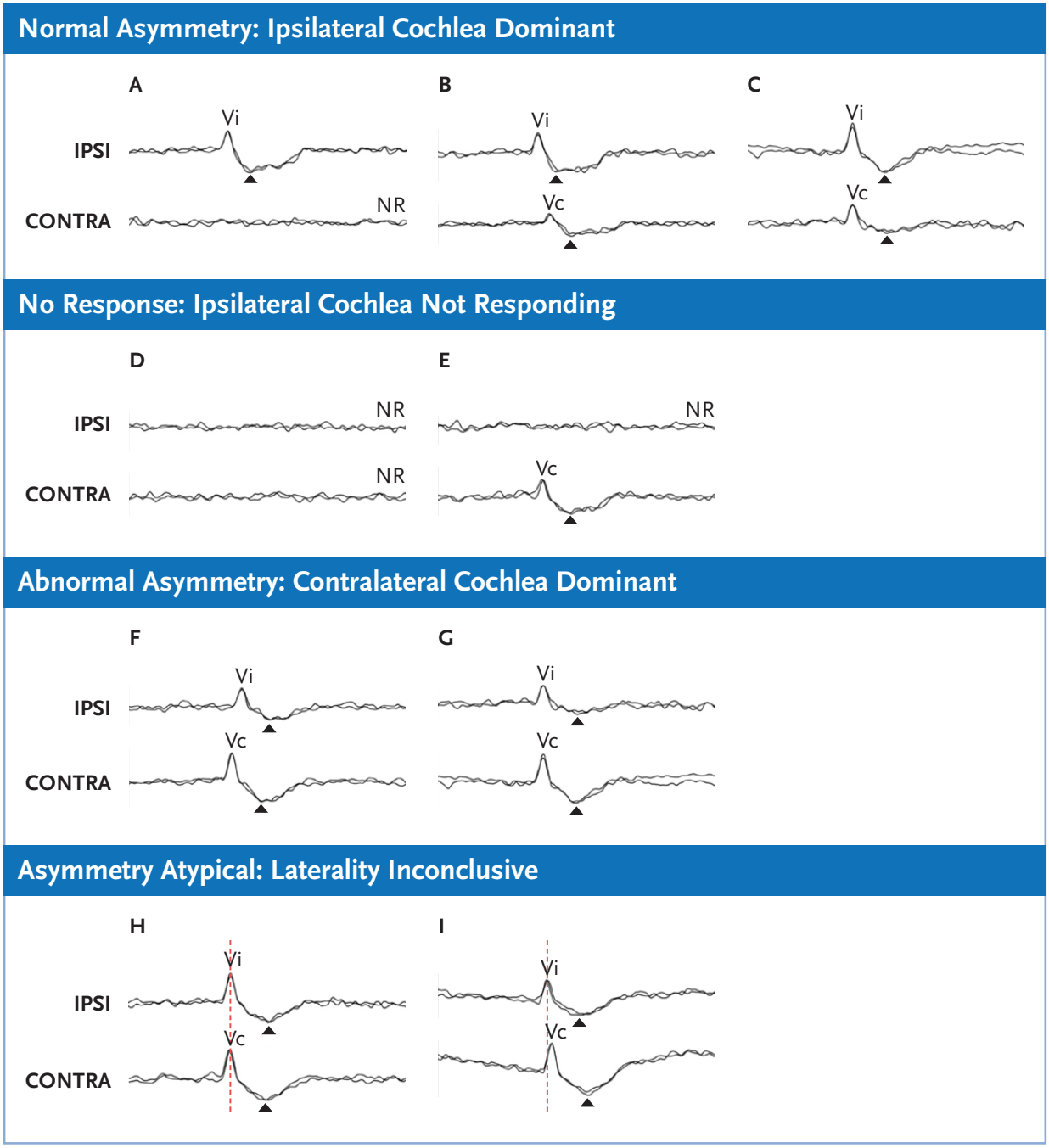


Figure 4.9.2: Interpretation of ipsilateral/contralateral EEG channel asymmetries in infant ABRs to BC and AC tones. See text for explanation.

Very often, however, abnormal results show responses in both channels, with the contralateral channel showing "better" results. Example F shows both earlier and larger wave V-V' in the contralateral channel; example G shows similar latencies but larger V-V' amplitude in the contralateral channel. Both F and G are abnormal asymmetries indicating the contralateral cochlea is dominant, and suggest a sensorineural component in the ipsilateral cochlea. To reiterate, examples E, F and G are considered "abnormal" asymmetries and suggest the ipsilateral cochlea has either not responded (E) or is not responding normally (F and G). **Importantly, when testing at levels above the normal minimum intensity, the possibility of a small response from the ipsilateral cochlea cannot be ruled out by F or G patterns, although it is likely ipsilateral threshold is greater than the stimulus intensity. In the case of obtaining F or G patterns at higher intensities, masking of the contralateral ear is usually required to confirm thresholds.**

ABR ipsilateral/contralateral results do not always point to the responding cochlea and thus are inconclusive. Example H shows latencies and amplitudes are the same in both channels. Example I shows earlier wave V latency in the ipsilateral channel but a clearly larger V-V' amplitude in the contralateral channel. In either case, it is not possible to determine the responding cochlea and one can only conclude "at least one cochlea has responded". Further testing involving masking of the contralateral ear would be required to determine response laterality (see below).

If the ipsilateral/contralateral response pattern does not allow one to determine response laterality (i.e., which cochlea is responding), *changing intensity, especially going down 10 dB, may isolate the responding side* (even by going below the normal minimum stimulus intensity if necessary). If none of these manoeuvres is successful, then contralateral broadband noise masking presented via an insert earphone is usually required to determine response origin. Insert earphones do not need to be removed for BC-ABR testing in infants aged 12 months or less, as young infants do not demonstrate the occlusion effect.

Wave I is usually not present in response to lower intensity stimuli (any frequency; BC and AC). It is also usually not present to low-frequency stimuli at even high intensities. However, if and when it is clearly present and can be differentiated from stimulus artifact (a problem with high-intensity BC stimuli), **wave I presence provides clear evidence of a response by the cochlea ipsilateral to the EEG channel showing the wave I**. Although not present in most BCEHP tone-ABR recordings, clinicians should keep an eye out for wave I presence when response laterality is an issue.

In summary, it should be clear that there are limitations to the inferences that can be made with wave V-V' ipsi/contra latency/amplitudes differences:

- *For stimulus intensities where acoustic crossover is a real possibility,* the simple presence of a response in either channel, by itself, does not indicate the cochlea on that side has responded. Thus, a response in the ipsilateral channel, by itself, does not mean that the cochlea on the stimulated side is necessarily responding. The ipsilateral waveform could be a shadow "contralateral" response from the contralateral cochlea. Similarly, by itself, a response in the contralateral channel does not necessarily imply that the contralateral cochlea has responded to the stimulus, as it may be the typical recording seen in the contralateral EEG channel to stimulation of the cochlea on the other side. Only by comparing the ipsilateral and contralateral response latencies and amplitudes can inference be made regarding response origin ("laterality").
- *For any stimulus intensity,* if the ipsilateral channel has a V-V' response that is better (earlier latency and larger amplitude) than in the contralateral channel, then the ipsilateral cochlea has responded. No inference about the contralateral ear is possible (patterns A, B & C).
- *For any stimulus intensity,* if the ipsilateral channel shows NR, then the ipsilateral cochlea has not responded. If there is NR in the ipsilateral channel but a response in the contralateral channel, it may be inferred that the contralateral channel has responded (a "shadow" response; patterns D & E).
- *When testing at normal minimum stimulus intensities (or lower),* if there is a response in both channels and the responding cochlea is inferred to be contralateral dominant, the stimulus intensity is low enough and interaural attenuation great enough (in young infants) to allow one to conclude the ipsilateral cochlea has not responded. The presence of the better response in the contralateral channel suggests normal responsivity in the contralateral cochlea; however, the contralateral cochlea should be directly tested (patterns F & G).
- *When testing above the normal minimum stimulus intensities,* if there is a response in both channels and the responding cochlea is inferred to be contralateral dominant, it is most likely that the ipsilateral cochlea has not responded. However, if the stimulus intensity is high enough to stimulate both cochleae, *the possibility of a small response from the ipsilateral cochlea cannot be ruled out.* Masking of the contralateral ear is usually required to confirm thresholds (patterns F & G).

- When laterality is inconclusive (patterns H & I), masking of the contralateral ear is usually required to confirm thresholds. However, if inconclusive at the normal minimum intensity, lowering the stimulus intensity by 10 dB may indicate laterality without the need for contralateral masking.
- The presence of wave I is good evidence of a response from the cochlea on the same side as the EEG channel it is seen in.

4.10 CONTRALATERAL AC MASKING DURING BC TESTING

BCEHP does not use contralateral masking as the first-line approach to ensuring activation of the desired cochlea with BC stimuli. However, when ipsi/contra EEG channel results are inconclusive as to laterality, or if they suggest origin from the contralateral cochlea (at levels above normal minimum intensity), combining AC contralateral masking with observation of ipsilateral/contralateral response asymmetries may be necessary to determine the responding cochlea. For safety reasons, contralateral masker level should not exceed 85 dB SPL.

BCEHP does not use contralateral masking as the first-line approach to ensuring activation of the desired cochlea with BC stimuli because it may not be easy to implement, it is limited in its highest intensity, it sometimes awakens the baby, and normative data on ipsilateral/contralateral ABR masking effects are limited. For these reasons, contralateral masking for BC stimuli is a discretional procedure. **Note that although masking is a discretional procedure, its application may be necessary in order to *interpret* results where laterality is inconclusive or, above the minimum stimulus intensities, where responses are contralateral dominant.**

Contralateral masking in BC tone-ABR threshold estimation is not usually required when any of the following is seen:

- the ipsilateral recording channel shows NR
- the contralateral recording channel shows NR
- neither channel shows a response
- the ipsilateral recording channel shows a response and the contralateral recording shows NR
- responses are seen in both the ipsilateral and contralateral channels, but the response in the ipsilateral channel is clearly better (earlier latency, larger amplitude) than the response in the contralateral channel

The need for contralateral masking in BC tone-ABR threshold estimation is limited to situations in which:

- *When testing at the normal minimum intensity,* response laterality is inconclusive, and decreasing stimulus intensity does not resolve laterality.
- *When testing above the normal minimum stimulus intensities,* both ipsilateral and contralateral channels show a clear response, but the ipsilateral recording does not show a clearly better – earlier and larger – response; in this case, although abnormal, one cannot be certain if the response comes from stimulation of both cochleae or solely from the contralateral cochlea.

BCEHP testing with BC stimuli usually begins at the minimum intensity without contralateral AC masking. In most cases, especially those with CHL, the ipsilateral/contralateral ABR asymmetries provide clear results. However, when the ipsilateral/contralateral asymmetries are inconclusive, AC masking of the contralateral ear (broadband noise presented via an insert earphone) should be considered.

Assuming infants demonstrate at least 10 dB of interaural attenuation for BC stimuli (Hansen & Small, 2010; Mackey et al., 2018; Small & Stapells, 2008; Yang, Stuart & Moushegian, 1987), and *testing is conducted at the normal minimum intensities,* 75 dB SPL and 65 dB SPL are recommended for 0.5 and 2 kHz, respectively.

When masking BC stimuli which are above the normal minimum intensities for BC stimuli, one must be concerned about higher masker intensities waking up the baby. In this case, even if not fully masked, it might be more prudent to continue to use the masker levels noted above for the minimum intensities and observe the effect of the masker. Even if contralateral masking cannot fully mask a response from the contralateral ear, comparisons of masked and unmasked waveforms often give a clear inference about which cochlea is responding, *especially if ipsilateral/contralateral response asymmetries are also assessed.*

- Maximum recommended masking levels for BC stimuli are as follows: (i) 0.5 kHz: 85 dB SPL for 30 dB nHL; and (ii) 2 & 4 kHz: 85 dB SPL for 50 dB nHL (Lau & Small, 2020). *For safety reasons, contralateral masker level should not exceed 85 dB SPL.*
- Based on the above, achieving effective masking for levels more than 10-20 dB and 10-30 dB above the minimum stimulus intensities for 0.5 kHz and 2 kHz, respectively, is thus difficult.
- When testing older infants (≥ 12 months), 0-dB interaural attenuation must be assumed, thus masking levels 10-dB higher than indicated above should be used, further limiting levels than can be effectively masked.

The following masking levels are recommended for infants under 12 months old (modified from Lau & Small, 2020):

	Air-Conduction Noise Masker Levels for BONE-CONDUCTION Stimuli (in dB SPL)		
BC STIM LEVEL (dB nHL)	**BC 0.5 kHz**	**BC 2 kHz**	**BC 4 kHz[&]**
20	75	55	55
30	85	65	65
40	*85	75	75
50	*85	85	85
60	N/A	*85	*85

[&]Masking levels for BC 4kHz stimuli are provisional, pending further investigation.

*85 dB SPL is the maximum allowed masker level thus responses may not be fully masked.

Combining AC contralateral masking with observation of ipsilateral/contralateral response asymmetries can help determine the responding cochlea when unmasked BC (or AC) results are inconclusive as to cochlear laterality (i.e., which cochlea is responding) and/or there is uncertainty about ipsilateral cochlear threshold. Figure 4.10.1 provides some examples where this combination contributes (or does not contribute) to results interpretation.

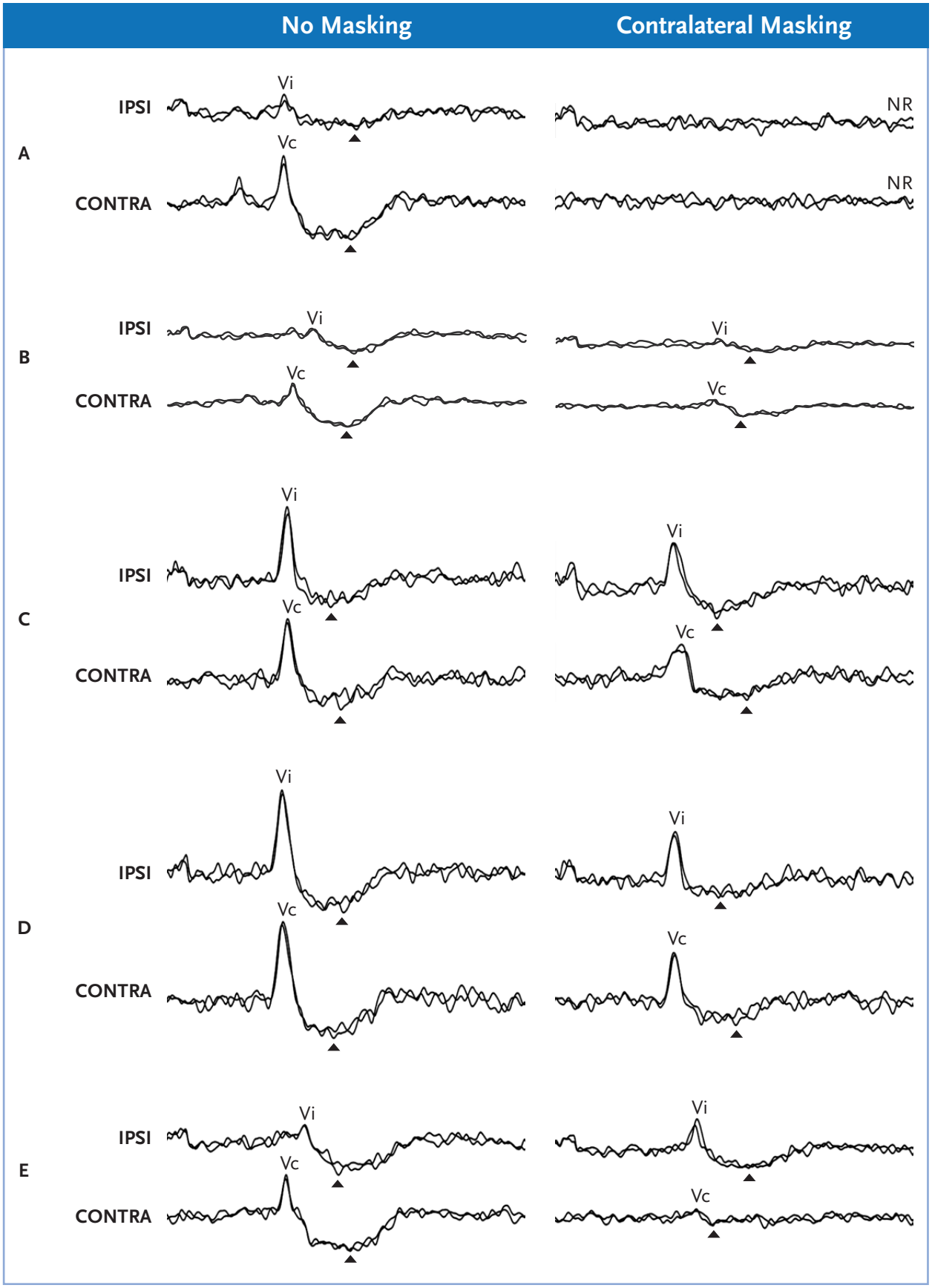


Figure 4.10.1: Some examples of wave V-V' ipsi/contra asymmetries and the possible effects of AC masking of the contralateral ear.

Some examples of ipsi/contra asymmetries and the possible effects of AC masking of the contralateral ear are shown in Figure 4.10.1. In most cases, these might be seen with either BC or AC stimuli at any intensity.

- In A, the non-masked ipsi/contra asymmetry is abnormal, with latency earlier and amplitude larger in the contralateral channel. Contralateral masking effectively masks the contralateral ear and, showing NR in either channel, masked results indicate no contribution from ipsilateral cochlea.
- In B, the non-masked condition shows abnormal asymmetry, suggesting contralateral dominance; masking only partially reduces the contribution from the contralateral cochlea and the ipsi/contra asymmetry remains abnormal, suggesting response is from the contralateral cochlea. This might be seen if effective masking of the contralateral ear is difficult due to masker intensity limits. In this case, threshold for the ipsilateral cochlea is likely above this stimulus level, however, a small contribution from the ipsilateral cochlea cannot be ruled out.
- In C, the non-masked condition shows inconclusive ipsi/contra results (same latency and amplitude); masking reduces contribution from the contralateral cochlea, so that contra is now later/smaller, thus the ipsi/contra asymmetry normalizes (ipsi becomes better than contra), suggesting the ipsilateral cochlea is contributing to the response.
- In D, laterality is inconclusive in the non-masked condition; masking reduces amplitudes in both channels, but ipsi/contra asymmetry remains inconclusive. In this case, one can only conclude "at least one cochlea responding".
- In E, the non-masked condition shows an abnormal asymmetry. Contralateral masking reduces/removes the contralateral cochlea contribution, such that the asymmetry normalizes, showing better results in the ipsi channel, indicating a response from the ipsilateral cochlea. This finding is more likely when testing higher intensity stimuli.

When testing BC at *the normal minimum intensity (or lower)* and an abnormal ipsi/contra asymmetry is seen (A and B in Figure 4.10.1), masking is not required to interpret this as being NR from the ipsilateral cochlea.

The patterns shown in Figure 4.10.1 are not all-encompassing; there are many possible combinations of stimuli, intensities, maskers and, importantly, hearing loss that could produce other patterns. In cases where "effective" contralateral masking could not be achieved (e.g., higher intensity stimuli and/or an infant who wakes up to higher intensity masking noise), the addition of lower masker levels, combined with observation of ipsi/contra asymmetries, may still reveal response origin.

4.11 CONTRALATERAL AC MASKING DURING AC TESTING

BCEHP does not use contralateral AC masking as the first-line approach to ensuring activation of the desired cochlea. When recording the ABR to AC stimuli (tones or clicks), if the threshold asymmetry is large (either ≥ 40-dB difference between thresholds when elevated, or if threshold is ≥ 60 dB nHL but only one ear elevated), clinicians must first switch to 2-channel EEG recordings and examine the ipsilateral-contralateral wave V asymmetries to determine response origin. However, as with BC testing, if the ipsilateral-contralateral asymmetries do not resolve response origin, or if they suggest origin from the contralateral cochlea, then masking of the contralateral ear with AC broadband noise may be necessary to determine the responding cochlea. For safety reasons, contralateral masker intensities should not exceed 85 dB SPL.

In ABR audiometry, masking of the contralateral ear during AC testing is not required in most cases, even when hearing loss is present. However, when AC tone-ABR thresholds indicate significant threshold asymmetry between ears at a given frequency (either ≥ 40-dB difference between thresholds when elevated, or if threshold is ≥ 60 dB nHL but only one ear elevated; see Section 3.6), then clinicians must take steps to determine which cochlea is responding to ensure responses to tones or clicks are not due to crossover stimulation. The primary method for this for AC stimuli is observation of wave V-V' ipsilateral/contralateral latency/amplitude asymmetries, as described in Section 4.9. *If the AC threshold asymmetry meets one of the criteria above, clinicians must switch to 2-channel EEG recordings and examine the ipsilateral-contralateral wave V asymmetries to determine response origin.*

Although BCEHP uses ipsi/contra asymmetries as its first-line approach for determining which cochlea is responding to AC stimuli, similar to testing with BC stimuli, in some cases masking of the contralateral ear with AC broadband noise (combined with observation of ipsi/contra asymmetries) is necessary to resolve response origin, especially when the ipsilateral-contralateral asymmetries are inconclusive. This is the same approach as for testing with BC stimuli (Section 4.10). As for BC stimuli, contralateral masking for AC stimuli is a discretional procedure. **Although masking is a discretional procedure, its application may be necessary in order to *interpret* results where laterality is inconclusive or where responses are contralateral dominant.**

In contrast to behavioural testing of older clients, ABR audiometry in infants does not have the time for plateau masking. Unfortunately, there are no well-established effective masker levels (EMLs) for infants for AC-ABR stimuli. The table below suggests AC broadband noise masker levels for AC stimuli. *Masker levels must not exceed 85 dB SPL.*

	Air-Conduction Noise Masker Levels for AIR-CONDUCTION Stimuli (in dB SPL)				
AC STIM LEVEL (dB nHL)	0.5 kHz	1 kHz	2 kHz	4 kHz	CLICKS
**60	65	65	45	60	55
70	65	65	45	60	55
80	75	75	55	70	65
90	85	85	65	80	75
100	*85	*85	75	*85	N/A

*85 dB SPL is the maximum allowed masker level, thus responses may not be fully masked. Levels are derived from Stapells (1984) and assume 30-dB of interaural attenuation. *Levels are only for AC stimuli, not BC stimuli.*

**Not recommended to reduce masking noise below the level suggested for 70 dB nHL.

As noted in Section 4.10, in cases where "effective" contralateral masking could not be achieved (e.g., higher intensity stimuli and/or an infant who wakes up to higher intensity masking noise), the addition of lower masker levels, combined with observation of ipsi/contra asymmetries, may still reveal response origin.

4.12 ESTIMATED HEARING LEVELS (EHL)

Tone ABR thresholds must be adjusted using "nHL to eHL Correction Factors" to provide an estimate of pure-tone behavioural threshold. Clinicians should expect deviations of as much as 5-10 dB and, occasionally (5% of time), as much as 15-20 dB. BCEHP correction factors are valid only for the stimulus parameters and recording techniques specified in this protocol.

Tone-ABR threshold estimates in dB nHL must be adjusted by the correction factors shown below in order to derive threshold estimates in dB eHL. For all conditions, when a clear response at BCEHP minimum stimulus intensity is found, the eHL will be deemed to be ≤ 25 dB eHL.

	BCEHP nHL to eHL Correction Factors (dB)			
	0.5 kHz	1 kHz	2 kHz	4 kHz
Air Conduction	-10	-10	-5	0
Bone Conduction	+5	*NA*	-5	-5[&]

NA: Not applicable (no reliable correction available)

[&]Correction factor for BC 4 kHz is preliminary

The purpose of ABR audiometry is the estimation of pure-tone hearing thresholds (dB HL). This is based on determination of tone-ABR threshold estimates in dB nHL, followed by adjustments that are based on known normative statistical relationships between tone-ABR and VRA-based behavioural thresholds.

ABR thresholds are generally not the same as true perceptual thresholds, but they are usually good predictors of them. ABR thresholds are adjusted to provide an *estimate* of pure-tone behavioural threshold, rather than a direct assessment of perceptual thresholds, hence the term "estimated hearing level (eHL)". The behavioural threshold estimated by the correction factors is the threshold with the highest probability. However, as with all such probability measures, clinicians must keep in mind that there is a range of possible true dB HL values for a given ABR threshold. The ABR audiometry protocol described in this document reduces this range of possible values; nevertheless, clinicians should expect deviations of as much as 5-10 dB and, occasionally, as much as 15-20 dB (5% of time) (Picton et al., 2005; Small & Stapells, 2017).

The correction factors used in this protocol are based on those derived by Martyn Hyde, who carried out a statistical re-analysis of published and unpublished normative data, particularly those of Stapells and his colleagues (reviewed by Small & Stapells, 2017). The corrections are similar to those used in the Ontario Infant Hearing Program (Baggato, 2020). The correction factor for a given stimulus route and frequency is based on the estimated population median difference in dB between reliable, paired ABR and VRA thresholds in large, representative groups of young infants. The overall value of the median difference (ABR minus VRA) is rounded to the nearest 5 dB, for simplicity of use.

There is a clinical impression that ABR thresholds are closer to behavioural thresholds when hearing loss is severe (e.g., McCreery et al., 2015), and this is often explained by appeal to a recruitment-like phenomenon. In conventional sensory hearing loss of the type affecting, first, the outer hair cells, then the inner hair cells as well, there is a weak tendency for the median threshold difference to decrease progressively above about 70 dB nHL. The convergence is approximately linear but is clinically insignificant *relative to other sources of bias and imprecision in* (i) behavioural threshold estimation (such as elevated VRA thresholds due to response habituation) as well as (ii) ABR technical factors such as recording time, response signal-to-noise ratio and spectral spread of ABR stimuli. These many factors influence the key elements in normative threshold relationships that determine the adjustments to derive eHL estimates. Such adjustments are dependent on stimulus frequency, but currently the best evidence is that they do NOT depend substantially

on stimulus level or, concomitantly, the true hearing level, over the range of interest in BCEHP threshold measurements. Accordingly, the *current BCEHP correction factors are specific to stimulus frequency but not to the observed ABR threshold level.*

BCEHP correction factors are valid only for the stimulus parameters and recording techniques specified in this protocol. They do not apply to estimation of hearing levels more than 5-10 dB lower than BCEHP target disorder limits (Stapells et al., 1995), and they cannot be assumed to apply to stimulation and recording methods that do not follow this protocol.

4.13 INTERPRETATION OF BC-ABR THRESHOLDS AND AIR-BONE GAPS

Determining the presence of a conductive component is reasonably straightforward when responses to BC stimuli are present. A response to an AC stimulus at the normal minimum intensity indicates hearing within normal limits at that frequency, and thus no clinically significant conductive component. In contrast, an AC threshold greater than the minimum intensity combined with a present response to BC at the normal minimum indicate the presence of a CHL. BC-ABR thresholds are valid estimates of sensorineural hearing loss; however, differentiating mild SNHL and mild conductive losses can be difficult.

In the absence of prior BC-ABR information, all BC-ABR testing should begin at the specified minimum intensities, as ipsilateral/contralateral asymmetries are easiest to assess at these levels. When properly conducted, BC-ABR thresholds are valid estimates of sensorineural hearing loss (Hatton, Janssen, & Stapells, 2012).

Determining the presence of a conductive component is reasonably straightforward when responses to BC stimuli are present. Responses to AC stimuli at the normal minimum intensity indicate hearing within normal limits at that frequency, and thus no clinically significant conductive component. In contrast, AC thresholds greater than the minimum intensity combined with a present response to BC at the normal minimum indicate the presence of a CHL.

There are cases where it becomes difficult to determine the presence of a conductive component:

- Differentiating mild SNHL and mild conductive losses can be difficult, given that estimation errors for calculating eHLs for AC and BC are combined (see below). For example, an AC 2 kHz threshold of 40 dB nHL and BC 2 kHz present at the normal minimal level of 30 dB nHL might indicate a mild conductive loss. However, given the eHL estimation errors, it is also possible that this is a mild SNHL. *The solution, in these restricted cases, is to test BC at 10 dB nHL lower than the normal minimum intensity for BC when AC threshold are elevated by only 10 dB nHL* (i.e., 40 dB nHL at AC 2 kHz or 45 dB nHL at AC 0.5 kHz). Most infants with normal hearing (> 80%) show responses at these levels (Stapells, 1989; Stapells & Ruben, 1989). A response to BC present at 10 dB below the minimum when AC thresholds are elevated 5-10 dB above the minimum indicates a mild conductive component.
- Conductive components are difficult to quantify/determine for mixed losses where NRs to BC stimuli are present at the maximum BC intensities. This is because maximum stimulus intensities for BC tonepip stimuli are at lower levels than AC stimuli (i.e., 50-60 dB nHL maximum levels for BC versus 100 dB nHL for AC).

- Occasionally, in cases of severe/profound SNHL, there may be an unexpected response to 0.5 kHz BC tones presented at the highest intensities (> 40 dB nHL). When it does occur, this response is hard to differentiate from a typical threshold-level response. The origins of this response are, as yet, undetermined but may be associated with responses from the vestibular system.[7] Similar unexpected results have been seen in the auditory steady-state responses to low-frequency BC stimuli (e.g., Small & Stapells, 2004). Consideration of all results (including middle-ear tests) should help in the interpretation of such unexpected results.

Determining the *exact size* of the conductive component can be problematic. As is commonly done clinically with behavioural results, the BC threshold estimate may be subtracted from the AC estimate in order to derive an estimated air-bone gap. The following important points must be considered when interpreting such gaps:

- When responses are present at normal minimum stimulus intensities, testing at lower intensities is not typically pursued in these ABR audiometry protocols. Thus, air-bone gaps calculated using these "non-threshold" normal minimum values are not true estimates of the size of the air-bone gap.
- Estimated behavioural HLs (eHLs) are statistical estimates of true perceptual thresholds, and each nHL-to-eHL conversion may contain estimation error of 5-10 dB in either direction; when subtracting one threshold (BC) from another (AC), these errors combine (add), in either direction. Thus, errors may be as much as 10-20 dB.
- If the correction factors are chosen appropriately, on occasion small negative air-bone gaps (i.e., when the BC threshold is higher than AC threshold) of up to -10 dB may be seen. These should be disregarded completely, and the AC threshold should be considered as valid. If a negative gap of 15 dB or more is observed, the accuracy of the threshold estimates should be reviewed carefully (e.g., the BC response threshold estimate may be too high or the AC threshold too low).
- As already noted, an elevated AC threshold combined with a normal BC result normally indicates the presence of a conductive component. From the above, however, the calculated air-bone gap is not always accurate. Even behavioural air-bone gaps show considerable variability (Margolis, 2008). Therefore, a positive gap of 15 dB or less should not be considered as an accurate representation of the true air-bone gap unless accompanied by a clearly abnormal tympanogram. As described above, when AC thresholds are elevated by only 10 dB and BC ABR is present at the normal minimum intensity, it is recommended to test BC at 10 dB below the BC normal minimum. *Positive gaps of 20 dB or more should be considered as genuinely indicative of a conductive component,* except when accompanied by a clearly normal tympanogram, in which case the thresholds leading to the gap should be reviewed carefully.

Given the defined minimum levels and the obtainable maximum levels for BC of 60 dB nHL at 2 kHz and 50 dB nHL at 0.5 kHz, the effective dynamic range of positive gaps is only about 30-35 dB. Given the possible variability of gap estimates, actual clinical inferences from comparing AC and BC threshold estimates *when BC is elevated* are: (i) "no indication of a significant conductive component" (gaps ≤ +15 dB), (ii) "mild conductive component" (gaps of 20-25 dB) and (iii) "substantial conductive component" (gaps ≥ 30 dB). Of course, if there is an AC threshold estimate of > 60 dB eHL and NR at BC maximum level, a reliable inference of absent conductive component cannot be made, except tentatively on the basis of tympanometry.

[7] There are several reports of a short-latency (3-4 ms) negative-going potential ("N3") in response to clicks in some patients with enlarged vestibular aqueduct and profound hearing loss (Figure 21.8 in Small & Stapells, 2017). This seems different from the later, positive-going, wave-V-like response to 0.5 kHz BC tones.

4.14 EXAMPLE ABR AUDIOMETRY TEST SEQUENCES

Sample ABR audiometry test sequences for infants with normal hearing or hearing loss are provided.

Sample test sequences for infants with normal hearing, conductive loss and SNHL are provided below. With the exception of sequences for normal hearing, the possible sequences for infants with hearing loss are not limited to the sequences in the examples below. Sequences, however, will normally adhere to principles outlined above in Sections 4.1, 4.2 and 4.3, with the goal of obtaining the mandatory results indicated in Section 4.4. Reasons for deviating from these principles can occur but must be documented by the ABR Audiologist when they occur.

EXAMPLE SEQUENCES FOR NORMAL HEARING

Alternative A:

1. Ear #1: AC2k@30dB nHL → [RP]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #2: AC0.5k@35dB nHL → [RP]
4. Ear #1: AC0.5k@35dB nHL → [RP]
5. Ear #1: AC4k@25dB nHL → [RP]
6. Ear #2: AC4k@25dB nHL → [RP]

Mandatory components completed above

Discretional components (*) may be assessed if baby still asleep:

7. Ear #2: AC1k@35dB nHL → [RP]*
8. Ear #1: AC1k@35dB nHL → [RP]*

Alternative B:

1. Ear #1: AC2k@30dB nHL → [RP]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #1: AC4k@25dB nHL → [RP]
4. Ear #2: AC4k@25dB nHL → [RP]
5. Ear #2: AC0.5k@35dB nHL → [RP]
6. Ear #1: AC0.5k@35dB nHL → [RP]

Mandatory components completed above

Discretional components (*) may be assessed if baby still asleep:

7. Ear #2: AC1k@35dB nHL → [RP]*
8. Ear #1: AC1k@35dB nHL → [RP]*

Normal test sequence explanation:

- In the absence of prior ABR audiometry results, testing must begin by AC at the 2 kHz normal minimum of 30 dB nHL in each ear.
- For most infants, if both insert earphones are placed and thus ear switching is easy, pick either ear and do AC 2 kHz at 30 dB nHL. Regardless of RP or NR for the first ear, switch ears and do AC 2 kHz 30 dB nHL for the other ear. If both ears show clear RP to AC 2 kHz 30 dB nHL, then this condition is normal. Switch to another stimulus frequency, which may be 0.5 (Alternative A) or 4 kHz (Alternative B), and test at the normal minimum intensity.
- Clinicians may prefer to test 4 kHz after 2 kHz (Alternative B) because responses for normal ears to 4 kHz at the normal minimum intensity (25 dB nHL) are typically easy and quick to identify (sometimes with only 1000 sweeps per replication). Responses to 0.5 kHz at 35 dB nHL can be less obvious and may require additional averages. Responses to AC 0.5, 2.0 and 4 kHz at the normal minimum intensities are mandatory to determine normal hearing for an ear. As both 0.5 and 4 kHz are required to complete ABR audiometry, when testing normal ears, it is discretional which of these frequencies is tested first. After all mandatory testing has been completed for both ears, clinicians may discretionally assess AC 1 kHz at the 35 dB nHL normal minimum.

EXAMPLE SEQUENCES FOR UNILATERAL PRESUMED TEMPORARY CHL (ACCOMPANIED BY FLAT TYMPANOGRAM(S))

Example 1 (Moderate CHL Ear #1):

1. Ear #1: AC2k@30dB nHL → [NR]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #1: BC2k@30dB nHL → [RP]
4. Ear #1: AC2k @60dB nHL → [RP]
5. Ear #2: AC4k@25dB nHL → [RP]
6. Ear #2: AC0.5k@35dB nHL → [RP]

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

7. Ear #1: BC0.5@20dB nHL→ [RP]*
8. Ear #1: AC2k@40dB nHL → [NR]*
9. **Ear #1: AC2k@50dB nHL → [RP] =T***
10. Ear #1: AC0.5k@55dB nHL→ [NR] *
11. **Ear #1: AC0.5k@65dB nHL → [RP] =T***
12. **Ear #1: AC4k@55dB nHL → [RP] =T***
13. Ear #1: AC4k@45dB nHL → [NR] *
14. Ear #2: AC1k@35dB nHL → [RP]*
15. Ear #1: AC1k@45dB nHL → [NR]*
16. **Ear #1: AC1k@55dB nHL → [RP] =T***

Example 2 (Mild CHL, Ear #2):

1. Ear #1: AC2k@30dB nHL → [RP]
2. Ear #2: AC2k@30dB nHL → [NR]
3. Ear #2: BC2k@30dB nHL → [RP]
4. Ear #1: AC0.5k@35dB nHL → [RP]
5. Ear #1: AC4k@25dB nHL → [RP]
6. Ear #2: AC2k @60dB nHL → [RP]

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

7. Ear #2: BC0.5@20dB nHL→ [RP]*
8. **Ear #2: AC2k@40dB nHL → [RP] =T***
9. **Ear #2: AC0.5k@55dB nHL → [RP] =T***
10. Ear #2: AC0.5k@45dB nHL → [NR] *
11. **Ear #2: AC4k@35dB nHL → [RP] =T***
12. Ear #2: AC4k@25 dB nHL→ [NR] *
13. Ear #2: BC2k@20 dB nHL→ [RP]*
14. Ear #1: AC1k@35dB nHL → [RP]*
15. **Ear #2: AC1k@55 dB nHL → [RP] =T***
16. Ear #2: AC1k@45 dB nHL → [NR]*

Unilateral CHL test sequence explanation:

- If one or both ears show NR to AC 2 kHz 30 dB nHL, in most cases, the next step *after* testing AC 2 kHz at 30 dB nHL for each ear is to test BC 2 kHz at 30 dB nHL (normal minimum intensity for BC 2 kHz) in the ear(s) showing NR. The immediate question is not "what is the precise AC threshold?" but "is this abnormality sensorineural?" As the majority of infants with elevated AC thresholds will turn out to have conductive loss, switching to BC will most often quickly identify an infant's elevation as conductive in nature, providing important information for subsequent management and for the caregivers.
- If AC and BC testing at 2 kHz reveals a conductive component (e.g., RP at BC normal minimum intensity), a conductive component at 0.5 kHz may be assumed and its proof by 0.5 kHz BC is discretional. (The converse is not true; if a conductive component at 0.5 kHz is proven, it cannot be assumed that abnormality at 2 kHz is conductive, and absence of a sensory component at 2 kHz must be proven.) In other words, inference of conductive loss at 0.5 kHz does not imply that a loss at higher frequencies also must be conductive; whereas, if a loss at 2 kHz is purely conductive, it is reasonable to assume that a loss at 0.5 kHz is also conductive.
- After determining normal BC 2 kHz results, some ABR audiologists find it easiest and least disruptive to the infant to continue with BC testing and thus switch to BC 0.5 kHz at 20 dB nHL (normal minimum stimulus intensity). Alternatively, some clinicians return to AC testing. The choice is discretional.

- In the case of a very mild elevation for AC (AC 2 kHz threshold of 40 dB nHL in example #2 above) *and* response to BC at normal minimum intensity level (BC 2k at 30 dB nHL), showing a RP to BC at 10 dB below the minimum intensity can increase confidence that the loss is truly conductive in nature.
- The mandatory requirements above satisfy the minimum information needed in cases of uncomplicated temporary CHL accompanied by flat tympanograms. Further testing, such as establishing an AC threshold range for more than one frequency and completion of 0.5 kHz BC, is highly recommended, especially for children with identified risk factors including cleft palate/craniofacial anomalies.

EXAMPLE SEQUENCE FOR UNILATERAL MICROTIA/ATRESIA (INSERT EARPHONE CONTRAINDICATED)

Example (Moderate CHL Ear#2):

1. Ear #1: AC2k@30dB nHL → [RP]
2. Ear #1: AC0.5k@35dB nHL → [RP]
3. Ear #1: AC4k@25dB nHL → [RP]
4. Ear #2: AC2k@30dB nHL → [NR] (supra-aural headphone)
5. Ear #2: BC2k@30dB nHL → [RP]
6. Ear #2: BC0.5k@20dB nHL → [RP]
7. Ear #2: AC2k @60dB nHL → [RP] (supra-aural headphone)

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

8. Ear #2: BC4k@30dB nHL → [RP]*
9. **Ear #2: AC2k@50dB nHL → [RP]=T*** (supra-aural headphone)
10. Ear #2: AC2k@40dB nHL → [NR]* (supra-aural headphone)
11. Ear #2: AC0.5k@55dB nHL→ [NR]* (supra-aural headphone)
12. **Ear #2: AC0.5k@65dB nHL → [RP]=T*** (supra-aural headphone)
13. **Ear #2: AC4k@55dB nHL → [RP]=T*** (supra-aural headphone)
14. Ear #2: AC4k@45dB nHL → [NR] *(supra-aural headphone)
15. Ear #2: AC1k@55dB nHL → [RP] (supra-aural headphone)
16. Ear #2: AC1k@35dB nHL → [NR]* (supra-aural headphone)
17. **Ear #2: AC1k@45dB nHL → [RP]*=T** (supra-aural headphone)

Unilateral microtia/atresia test sequence explanation:

- Presuming an insert earphone is contraindicated in the ear with microtia/atresia, first quickly confirm normal hearing in the non-atretic ear. If results are not normal in that ear, proceed according to the ABR protocol for temporary conductive or permanent SNHL.
- In regard to AC for the ear with microtia/atresia, first determine that there is no pinhole opening and normal hearing *by testing AC 2 kHz using a supra-aural headphone.* If there is a RP in the normal range, continue testing AC on that ear. If there is NR, proceed to BC testing.

- If BC 2 kHz results are normal (30 dB nHL), continue with BC testing at 0.5 kHz (20 dB nHL). If not normal, BC thresholds are required. For children being considered for bone-anchored hearing systems (BAHS), knowledge of cochlear function is imperative. For this reason, BC 4 kHz may be assessed after all mandatory components are completed.
- Establishing an AC threshold range for at least one frequency (typically 2 kHz) is a mandatory requirement. Further testing, such as establishing an AC threshold range for multiple frequencies or AC thresholds using a 10-dB final step size can be undertaken if time permits. One might expect higher AC thresholds with more bony versus cartilaginous involvement in the atretic ear.

EXAMPLE SEQUENCES FOR SENSORINEURAL HEARING LOSS

Example 1 (Mild to moderate SNHL Ear #1):

1. Ear #1: AC2k@30dB nHL → [NR]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #1: BC2k@30dB nHL → [NR]
4. Ear #1: BC2k@60dB nHL → [RP]
5. Ear #1: BC2k @40dB nHL → [NR]
6. **Ear #1: BC2k@50dB nHL → [RP]=T**
7. Ear #2: AC4k@25dB nHL → [RP]
8. Ear #2: AC0.5k@35dB nHL→[RP]
9. **Ear #1: AC2k@50dB nHL → [RP]=T**
10. Ear #1: AC2k@40dB nHL → [NR]
11. Ear #1: AC0.5k@35dB nHL→ [NR]
12. **Ear #1: AC0.5k@45dB nHL → [RP]=T**
13. **Ear #1: AC4k@65dB nHL → [RP]=T**
14. Ear #1: AC4k@55dB nHL → [NR]

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

15. Ear #1: BC0.5k@20dB nHL → [NR]*
16. **Ear #1: BC0.5k@30dB nHL → [RP]=T***
17. Ear #1: AC1k@35dB nHL → [NR]*
18. **Ear #1: AC1k@45dB nHL → [RP]=T***
19. Ear #2: AC1k@35dB nHL → [RP]*

Example 2 (High-frequency 4 kHz SNHL bilateral):

1. Ear #1: AC2k@30dB nHL → [RP]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #1: AC0.5k@35dB nHL → [RP]
4. Ear #2: AC0.5k@35dB nHL → [RP]
5. Ear #1: AC4k@25dB nHL → [NR]
6. Ear #2: AC4k@25dB nHL → [NR]
7. **Ear #2: AC4k@55dB nHL → [RP]=T**
8. Ear #2: AC4k@35dB nHL → [NR]
9. Ear #2: AC4k@45dB nHL → [NR]
10. Ear #1: AC4k@55dB nHL → [RP]
11. Ear #1: AC4k@35dB nHL → [NR]
12. **Ear #1: AC4k@45dB nHL → [RP]=T**
13. Ear #1: AC2k@20dB nHL → [RP]
14. Ear #2: AC2k@20dB nHL → [RP]

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

15. Ear #1: BC4k30dB nHL → [NR]*
16. **Ear #1: BC4k50dB nHL → [RP]=T***
17. Ear #1: BC4k40dB nHL → [NR]*
18. Ear #2: BC4k50dB nHL → [NR]*
19. **Ear #2: BC4k60dB nHL → [RP]=T***
20. Ear #1: AC1k35dB nHL → [RP] *
21. Ear #2: AC1k@35dB nHL → [RP] *

Example 3 (Severe-profound SNHL, bilateral):

1. Ear #1: AC2k@30dB nHL → [NR]
2. Ear #2: AC2k@30dB nHL → [NR]
3. Ear #1: BC2k@30dB nHL → [NR]
4. Ear #1: BC2k@60dB nHL → [NR]
5. Ear #2: BC2k@30dB nHL → [NR]
6. Ear #2: BC2k@60dB nHL → [NR]
7. Ear #1: AC2k@80dB nHL → [NR]
8. Ear #2: AC2k@80dB nHL → [NR]
9. Ear #1: AC2k@100dB nHL → [RP]
10. **Ear #1: AC2k@90dB nHL → [RP] =T**
11. Ear #2: AC2k@100dB nHL → [NR]
12. Ear #1: AC0.5k@75dB nHL → [NR]
13. Ear #2: AC0.5k@75dB nHL → [NR]
14. **Ear #1: AC0.5k@95dB nHL → [RP] =T**
15. Ear #1: AC0.5k@85dB nHL → [NR]
16. Ear #2: AC0.5k@100dB nHL → [NR]
17. Ear #1: AC4k@100dB nHL → [NR]
18. Ear #2: AC4k@100dB nHL → [NR]
19. Ear #1: AC RC@90dB nHL → [NR]
20. Ear #1: AC CC@90dB nHL → [NR]
21. Ear #1: AC Clamp @90dB nHL → [NR]
22. Ear #2: AC RC@90dB nHL → [NR]
23. Ear #2: AC CC@90dB nHL → [NR]
24. Ear #2: AC Clamp @90dB nHL → [NR]

Mandatory components completed above

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

25. Ear #1: AC1k@100dB nHL → [NR]*
26. Ear #2: AC1k@100dB nHL → [NR]*
27. Ear #1: BC0.5k@50dB nHL → [NR]*
28. Ear #2: BC0.5k@50dB nHL → [NR]*

Example 4 (Mixed HL, Ear #1):

1. Ear #1: AC2k@30dB nHL → [NR]
2. Ear #2: AC2k@30dB nHL → [RP]
3. Ear #1: BC2k@30dB nHL → [NR]
4. Ear #1: BC2k@60dB nHL → [RP]
5. **Ear #1: BC2k@40dB nHL → [RP] =T**
6. Ear #2: AC0.5k@35dB nHL → [RP]
7. Ear #2: AC4k@25dB nHL → [RP]
8. Ear #1: AC2k@60dB nHL → [NR]
9. Ear #1: AC2k@80dB nHL → [RP]
10. **Ear #1: AC2k@70dB nHL → [RP] =T**
11. Ear #1: AC0.5k@55dB nHL → [NR]
12. **Ear #1: AC0.5k@75dB nHL → [RP] =T**
13. Ear #1: AC0.5k@65dB nHL → [NR]
14. **Ear #1: AC4k@80dB nHL → [RP] =T**
15. Ear #1: AC4k@70dB nHL → [NR]

Mandatory components completed above (note that 2-channel recordings are required for Ear #1 AC testing at or above 60dB nHL)

T=Threshold

Discretional components (*) may be assessed if baby still asleep:

16. Ear #1: BC0.5k@20dB nHL → [NR]*
17. Ear #1: BC0.5k@50dB nHL → [RP]*
18. **Ear #1: BC0.5k@30dB nHL → [RP] =T***
19. **Ear #1: AC1k@75dB nHL → [RP] =T***
20. Ear #1: AC1k@65dB nHL → [NR]*
21. Ear #2: AC1k@35dB nHL → [RP]*

Sensorineural hearing loss test sequence explanation:

- As previously mentioned, if one or both ears show NR to AC 2 kHz 30 dB nHL, in most cases, the next step is to test BC 2 kHz 30 dB nHL (normal minimum intensity for BC 2 kHz) in the ear(s) showing NR. If either or both ears show NR at BC 2 kHz at 30 dB nHL, then the next step is to begin a BC threshold SEARCH and assess BC 2 kHz at the maximum stimulus intensity (60 dB nHL). If there is a RP at BC 2 kHz 60 dB nHL, test either 40 or 50 dB nHL, depending on response morphology at 60 dB nHL, then ensure threshold bracketed using 10-dB steps. IF NR at BC 60 dB nHL, BC 2 kHz testing is finished for that ear.
- After demonstrating a unilateral SNHL component at 2 kHz, one can optionally further demonstrate normal results for the other ear (0.5 and 4 kHz), as done in Example #1 above, or assess the ear with SNHL.
- Following confirmation of a sensorineural component, a threshold search and bracket should be completed for AC 2 kHz. Assessment of other AC frequencies is next completed (typically AC 0.5 kHz, followed by AC 4 kHz, and AC 1 kHz, where indicated), with starting intensities usually determined by results at other frequencies. For example, with thresholds of 60 dB nHL or better at 2 kHz, testing at 0.5 kHz usually starts at the minimal level of 35 dB nHL (due to likelihood of high-frequency loss), whereas testing at 4 kHz could begin at the threshold level determined for AC 2K (4 kHz thresholds often worse than 2 kHz). Higher starting intensities may be considered if 2 kHz threshold is greater than 60 dB nHL: testing for 4 kHz (AC only) could begin at the 2 kHz threshold; testing for lower frequencies could start 10-20 dB nHL lower.
- Note then when SNHL has been confirmed at 2 kHz (and conductive overlay not suspected), 0.5 kHz BC testing is not required, but if done discretionally, it should only be pursued after all other mandatory protocol elements have been completed.
- BC 0.5 kHz must be done if AC 0.5 kHz is the only elevated threshold but is discretional if both AC 0.5 and AC 2 kHz are abnormal.
- If BC threshold for either (or both) 2 and 0.5 kHz are elevated, as indicated by a NR at the normal minimum stimulus intensity, then threshold search and bracket (within 10-dB) must be completed (up to the maximum stimulus intensity).
- AC at 1 kHz must be done if there is a difference of greater than 20 dB (in dB nHL) between the AC thresholds at 0.5 and 2 kHz. If the difference is less than 25 dB, testing at 1 kHz is discretional but not recommended unless all other mandatory ABR measurements have been completed.
- If 4 kHz is the only AC elevation, once the threshold at 4 kHz has been bracketed, testing at AC 2 kHz at 20 dB nHL is mandatory. This will enable calculation of a more accurate unaided speech intelligibility index (SII) value, which has a significant impact on the child's eligibility for early intervention services and amplification funding. In addition, BC 4 kHz may also be helpful.

For all test sequences: Whenever hearing loss is identified, clinicians should double-check for proper insert-earphone placement, rule out eartip occlusion, confirm stimulus audibility and ensure that electrode montage is correct and their impedances are still within target. This check should be conducted as soon as an AC elevation has been determined rather than at the end of the appointment in the event that a setup error is identified which would render results uninterpretable.

5 AUDITORY NEUROPATHY SPECTRUM DISORDER (ANSD) SUBPROTOCOL

5.1 ANSD OVERVIEW

Research suggests that up to 10% of PHL may have an ANSD component. The site of lesion for ANSD is not the outer hair cells (OHCs); rather, ANSD is related to abnormalities of the inner hair cells (IHCs), their synaptic linkages to auditory nerve fibres, or the auditory nerve fibres themselves. In between "normal ABR" and "absent ABR" lies a spectrum of ABR abnormalities within which differential identification of an ANSD component can be very challenging. Therefore, the ANSD subprotocol records the ABR to high-intensity clicks, with the intention to measure, when present, both the CM and neural ABR potentials above baseline residual noise and stimulus artifact if present.

Current evidence suggests that 7-10% of infants who have a moderate or greater degree of PHL may have ANSD. So-called "conventional" cochlear hearing loss affects the OHCs first and at greater severities usually also involves loss or damage to the IHCs and supporting structures. In contrast, ANSD is a disorder that is not known to affect OHC function but reflects abnormalities of the IHCs, their synaptic linkages to auditory nerve fibres or the auditory nerve fibres themselves. Only the last of these alternatives is a true neuropathy, but in 15-20% of all ANSD cases there is MRI evidence of dysgenesis or agenesis of the cochlear nerve. It cannot be assumed that only one site or mechanism of ANSD expression is necessarily involved in any given individual, nor that a more conventional cochlear hearing loss is not coexistent. (For a detailed explanation on the pathophysiologic mechanisms of ANSD, see Rance & Starr, 2015).

ANSD, conventional sensory hearing loss and CHL can all occur concurrently. ANSD may be unilateral or bilateral. A necessary (but not sufficient) condition for ANSD presence is a completely absent ABR or a highly abnormal waveform with absent, small or grossly delayed wave V-V' complex. The challenge is to identify and disentangle the components and to know when detection of ANSD is not possible. OAEs and CMs are important tools but are not equivalent clinically. CM presence does not necessarily rule out sensory hearing loss nor rule in ANSD.

One functional result of ANSD-type pathology is a deficiency in the number and/or the temporal pattern of afferent nerve impulses elicited by sounds. Such abnormalities have a range of perceptual sequelae that are measurable behaviourally in older children and adults. Notably, children with ANSD may have reduced abilities to detect temporal modulations of sound and difficulties with speech perception in noise that are more marked than in cases of conventional cochlear pathology with matched severity of sensitivity loss.

A further complication for ANSD identification is that some ANSD phenotypes appear to share etiologies (such as severe perinatal hypoxia) with conventional cochlear hearing loss. Because there is no reason to assume that ANSD, conventional cochlear hearing loss and CHL are necessarily mutually exclusive, they are referred to here as ANSD, conventional sensory hearing loss and CHL components.

Mismatch between gross measures of OHC and afferent neural function is the initial hallmark of ANSD. There are two main criteria for identifying ANSD. The first necessary (but not sufficient) criterion for ANSD identification is to establish a dysfunction of the transduction of sound by the IHCs and/or the neural transmission to the brainstem. A completely absent ABR or a highly abnormal ABR waveform with absent, small or grossly delayed wave V-V' complex should be used to determine this. At present, it is widely (but not universally) accepted that any elicitation of normal amplitudes and latencies of waves I through V rules out ANSD. A completely absent ABR to a high-intensity click stimulus indicates that an ANSD component

may be possible, but other causes include profound IHC/OHC-based sensory hearing loss and mixtures of it with CHL. Between normal and absent ABR lies a spectrum of ABR abnormality within which differential identification of an ANSD component can be very difficult.

The second necessary criterion is to establish that OHCs are responding typically to sound. The best indicators of normal OHC function are *present* OAEs. The presence of a CM is another possible indicator of OHC functionality, but it is not equivalent clinically to OAEs. This is because the IHCs and OHCs both contribute to the overall CM waveform (although the IHC contribution to the CM is typically small). Thus, a small CM may be generated by IHCs even if the OHCs are extensively damaged. Moreover, CMs recorded using typical ABR electrode placements (e.g., on the mastoid) may arise from any part of the cochlea, not necessarily the 1-4 kHz region that normally dominates the click ABR at high levels. This raises the concern of comparing phenomena from what may or may not be different parts of the cochlea, parts that might be subject to different pathophysiology. Another challenge with using the CM is to disentangle it from the neural potentials and/or stimulus artifact that may be present within the ABR. CM presence alone does not necessarily rule out sensory hearing loss nor rule in ANSD.

A major limitation of OAEs for ANSD assessment is that they are reduced or abolished by even mild CHL. Therefore, while OAE *presence* is highly informative, OAE absence is not. When both OAEs and the ABR are absent, several possible explanations exist: (i) severe-profound IHC/OHC-based sensory hearing loss; (ii) severe IHC/OHC-based sensory hearing loss plus a conductive overlay; or (iii) ANSD. Conductive overlay could result in OAE absence, and this in turn could lead to ANSD being missed.

There are many possible result outcomes that are less well defined and less clear than the classic ANSD pattern of "present OAE and absent ABR", such as situations of abnormal but not absent ABR and/or reduced or partially present OAEs. In cases of poor ABR morphologies, the click may be more effective at ABR elicitation than a tone. Therefore, it is appropriate to try high-level clicks when ABR to high-level tones are absent or poorly defined. For these reasons, it is appropriate to measure click ABR and CM whenever the possibility of ANSD is indicated in the course of tone threshold estimation. Such measurement should be deferred until tone ABR thresholds are completed to 10-dB bracketing. Bracketing tone thresholds to 5 dB is *not* appropriate if the ANSD subprotocol indicates ANSD possibility.

The ANSD subprotocol records the ABR to high-intensity (90 dB nHL) clicks, with the intention to measure, when present, both the CM and neural ABR potentials, especially wave V. CM amplitudes are small and easily confused with stimulus electromagnetic artifacts. The subprotocol includes: (i) increased averaging (more trials = lower RN = ability to measure smaller responses), (ii) individual recordings to both condensation and rarefaction polarity stimuli, which help separate CM from neural potentials and (iii) clamped-tube (no-stimulus) recordings, which aid in differentiating physiologic responses (CM, I, V) from non-physiologic artifact (e.g., stimulus artifact).

5.2 ANSD SUBPROTOCOL ENTRY CRITERION

The ANSD subprotocol is mandatory if grand averages of AC 2 kHz at 80 dB nHL show NR (flat beyond 5 ms) or a wave V latency greater than 10 ms. If BC 2 kHz is normal, ANSD subprotocol is discretional. The ANSD subprotocol must be carried out for each ear that meets the ANSD subprotocol entry criterion or where ANSD is a possibility, or in just the ear of concern in cases of unilateral hearing loss, although click protocol for both ears might be helpful for comparison.

In each ear, the ANSD subprotocol must be carried out if all AC 2 kHz averages done at or above 80 dB nHL are either flat beyond 5 ms latency or show wave V latency greater than 10 ms. In the rare event that this

condition is satisfied using AC stimuli, but there is an unequivocally normal wave V (with normal ipsi/contra asymmetry) to BC 2 kHz at any level, the entry into the ANSD subprotocol is discretional. *All mandatory tone-ABR thresholds should be completed before entering the ANSD subprotocol.*

The ANSD subprotocol must be entered even if responses to other frequencies show clear normal response(s) at 80 dB nHL or lower. Many severe and most profound HL at 2 kHz, as well as steeply sloping hearing losses, will thus require the ANSD subprotocol.

ABR threshold definition and wave V clarity and latency are often much better defined at 2 kHz than at 0.5 kHz, so a rational ANSD flag is lack of a 2-kHz response with a wave V latency under 10 ms at any level above 75 dB nHL. This criterion is thus satisfied, for example, by results such as an NR at 80 dB nHL, a CNE at 100 dB nHL or a RP at 80 or 90 dB nHL with wave V latency greater than 10 ms.

The majority of ANSD is bilateral, but unilateral ANSD or asymmetric ANSD severity are possible. When a clear wave V-V' waveform is obtained (with wave V latency within normal limits well above threshold), the ANSD probability becomes close to zero. In cases of unilateral findings, if time is limited, the ANSD subprotocol need only be carried out on the ear of concern. When time permits, click-ABR on the non-suspect ear can be beneficial for comparison.

5.3 ANSD SUBPROTOCOL TIMING

The ANSD subprotocol is carried out *after* tone-ABR threshold measurement is completed for both ears (AC and BC). Often more than one ABR session will be needed to meet all mandatory requirements, including the ANSD subprotocol.

The ANSD subprotocol should be deferred until tone-ABR threshold measurement to 10-dB bracketing is completed for both ears (including AC and BC at mandatory frequencies).

Given that there is at least severe HL or ANSD present (or both), the requirement for the ANSD protocol sometimes is established early in the initial ABR audiometry appointment. However, it does not follow that the ANSD protocol should be entered prior to establishing mandatory tone-ABR thresholds. First, most cases of complete absence of ABR at 2 kHz at high intensities are caused by IHC/OHC-based PHL and not ANSD, thus tone-ABR thresholds are a reliable measure of peripheral hearing thresholds. The exception to this is if DPOAEs were measured prior to the ABR assessment (which is usually not the case) and are present. Second, testing at 0.5 and 4 kHz may be clinically useful even if ANSD is present because any measurable ABR strongly suggests auditory perceptibility at the evoking stimulus level or lower. Even abnormal ABRs in cases of ANSD can give clinically useful threshold upper bounds, and if the ABR is completely absent, the time spent confirming that for all key frequencies will be small. It follows that at least the basic threshold search phase for 2, 0.5 and 4 kHz in each ear should be attempted first, with 10-dB AC bracketing in the event that a late or degraded wave V is recognized.

ANSD presence does not necessarily invalidate tone-ABR thresholds. If a second ABR appointment is necessary, as is frequently the case, the opportunity to start the second session with OAEs may prove useful and efficient.

If and when ABR audiometry shows bilateral threshold elevation and at least one ear has the ANSD subprotocol indicated, it will be unlikely to be able to complete all the mandatory threshold protocol for both ears within the first ABR audiometry session. Thus, a second session will almost always be required to complete all testing, including the ANSD subprotocol.

5.4 ANSD TEST PROCEDURES

Clicks of 90 dB nHL, calibrated using BCEHP standards, must be used. When *both* CM and wave V are of low amplitude (< 0.1 µV p-p), the final RN must be less than 50% of the amplitude of CM and wave V. Separate "clamped-tube" no-sound condition recordings to RC and/or CC are also required.

The following procedures, waveform processing and measures are required for each ear for which the ANSD subprotocol entry criteria are met:

For all click-ABR averages:

- -2-ms to 12.8-ms data window
- EEG filters: 30-3000 Hz
- 90 dB nHL clicks
- Initial stimulus presentation rate 19.1/s (to be sped up to 91.1/s if required; see * below)
- Separate recordings to RC and CC
- Minimum of two recordings (each at least 1000, preferably 2000, sweeps) per RC and CC stimulus condition. As with tone ABR, in order to determine NR, the grand average RN must meet the usual ≤ 0.08 µV (≤ 0.04 µV if non-flat) noise requirements.
- In contrast to tone ABR, because ANSD assessment requires comparison between CM and wave V amplitudes, the ANSD click-ABR subprotocol has an additional noise requirement, even when responses are present, in order to ensure accurate measures. *Specifically, when **both** CM and wave V amplitudes are very small (< 0.1 µV p-p), the SmartEP RN amplitude must be no more than 50% of the CM and wave V peak-to-peak amplitudes.*[8] If not, additional trials/replications should be obtained to reduce the waveform RN (with RN=0.04 µV being the practical limit; i.e., no need to try to get RN lower than 0.04 µV). Regardless of RN, collecting a large number of replications (e.g., >4) for each of RC and CC is not recommended because of safety issues and reduced return on investment.
- In addition to the above, a separate recording to either RC or CC in the clamped-tube no-sound condition, meeting the ≤ 0.08 µV noise requirement (if clamp tube recording is not clearly flat in the first 0-3ms post-stimulus, then testing of the other polarity is required).
- Meeting the above RN requirements is always preferred. However, there are situations where RN requirements are not met but the result is clear. For example, (i) a large CM (> 0.2 µV p-p) and no identifiable wave V or (ii) a clear wave V and CM is not identifiable. The reliability of results in cases where RN is not met should be discussed with a PSA.

Mandatory Procedures:

- Slow-rate (19.1-21.1/s), separate recordings of RC and CC at 90 dB nHL (at least 2 replications for each polarity), for assessment of cochlear microphonic potentials (CM), cochlear summating potentials (SP) and neural components (ABR waves I to V presence, morphology, latency, amplitude)
- No-stimulus recordings to either RC or CC by clamping insert earphone tube (if clamp tube recording is not clearly flat in the first 0-3ms post-stimulus, then testing of both polarities is required)

[8] As described in Section 3.16, for a response to be detectable its peak-to-peak amplitude should be 1.25-1.5 times the SmartEP RN. Said differently, the SmartEP RN must be no more than 67-80% of the response amplitude. Both to simplify calculations during recordings and to be more conservative for the ANSD protocol, we have chosen 50% when both the CM and wave V are small.

- Determination of ANSD requires low-noise recordings, as responses with low peak-to-peak amplitudes are often assessed. When **both** CM and wave V amplitudes are very small (< 0.1 μV p-p), the SmartEP RN amplitude must be no more than 50% of the CM and wave V peak-to-peak amplitudes. If not, additional trials/replications should be obtained to reduce the waveform RN (with RN=0.04 μV being the practical limit; i.e., no need to try to get RN lower than 0.04 μV).
- Specific analyses are required for the above data: (i) RC and CC grand averages, (ii) the alternating polarity replications and their grand average (calculated by averaging sets of RC and CC averages), (iii) RC grand average and the CC grand average "butterfly" plot, (iv) either the RC-CC or CC-RC subtraction (from the RC and CC grand averages) and (v) grand average of the RC or CC clamped-tube no-sound condition.

Conditional Mandatory Procedures:

- If cochlear (CM and/or SP) potentials cannot be differentiated from wave I, then separate recordings using a very fast rate (91.1-101.3/s) of RC and CC at 90 dB nHL (at least 2 replications for each polarity), are required to help tease out cochlear from neural responses. For example, stimulating at this fast rate will often substantially reduce or remove neural potentials (especially wave I) but not the CM or summating potential, SP (both cochlear potentials).
- For unilateral hearing loss, 2-channel recordings are required. Masking may also be helpful. See Section 4.11 for when to use 2-channel recordings (and possibly masking).

Discretional Procedures:

- Click-ABR *threshold*, as part of the ANSD subprotocol. In very rare cases, the tone-ABR protocol may miss an island of better hearing that the broadband click-ABR reveals (i.e., NR to tones but clear wave V to clicks).
- Acoustic reflex measurements: They have some value as a crosscheck when ABRs are absent at high stimulus levels, in that reflex presence contradicts inference of both ANSD and profound conventional cochlear hearing loss. In general, reflex presence may be clinically informative, whereas reflex absence is rarely so. Acoustic reflex measures should only be obtained after all mandatory components have been completed.

5.5 MANDATORY ANALYSES AND DISPLAY

Waveform analyses and consistent display are mandatory in order to disentangle stimulus artifact, CM, SP and ABR neural potentials. Display should include: (i) RC and CC grand averages and their replications, (ii) the ALT polarity grand average and its replications, (iii) RC and CC grand average "butterfly" plot, (iv) either the RC-CC or CC-RC subtraction (from the RC and CC grand averages) and (v) clamped-tube no-sound grand average and its replications. Measures of CM peak-to-peak amplitude and waves I and V latency and amplitude must be marked (where possible).

Waveforms obtained using the above mandatory procedures require further processing and consistent display in order to disentangle: CM, stimulus artifact, cochlear summating potentials (SP) and ABR neural potentials (Figure 5.5.1).

- the RC and CC grand averages and their replications. This allows visualization of the stimulus artifact and any responses in each polarity and their replicability.

- "Alternating" (ALT) polarity replications calculated by averaging sets of RC and CC replications. The grand average of the ALT replications must also be calculated. This procedure removes most/all of non-neural potentials that alternate polarity with stimulus polarity (i.e., removes stimulus artifact and CM). The SP and neural responses remain. **NOTE:** if the number of sweeps in each recording in the calculation are identical, the "sweep-weighted" averaging procedure is used. However, **if one or more recordings differ in number of sweeps,** to give equal weighting to RC and CC, **the "µV-weighted" averaging ("addition" on the SmartEP) procedure must be used and the result multiplied by 0.5** (to make amplitude measures correct).
- The RC and CC grand averages displayed as a butterfly plot (superimposed at the first data point, i.e., the SmartEP "node") to help visualize the phase-dependent components of the CM as well as any latency-shifting neural components.
- The RC-minus-CC (RC-CC) *or* the CC-minus-RC (CC-RC) subtractions derived from the RC and CC grand averages. This procedure usually removes most of the neural potentials that do not alternate with changes in polarity. CM and stimulus artifact remain. **NOTE:** if the number of sweeps in each RC and CC grand average are identical, the sweep-weighted subtraction procedure is used. However, **if one or more recordings differ in number of sweeps**, to give equal weighting to RC and CC, **the µV-weighted subtraction procedure must be used and the result multiplied by 0.5** (to make amplitude measures correct).
- *Discretional:* Calculate both the RC-minus-CC (RC-CC) *and* the CC-minus-RC (CC-RC) and display as a butterfly plot. This plot helps visualize the phase-dependent components of the CM. This may make it easier to measure CM duration, which is currently under investigation by BCEHP and UBC.
- RC and/or CC clamped-tube no-sound condition grand averages if more than one replication has been obtained.

At a minimum, the following **measures** must be marked/obtained:

- On the ALT grand average: ABR waves I and V latency and amplitude measures (other waves are discretional). If wave V is larger on either RC or CC grand averages, mark latencies/amplitudes also on these.
- On the RC-CC and/or CC-RC, the largest CM peak-to-peak amplitude occurring within 0-3 ms post-stimulus (measure using the wave I label on either RC-CC or CC-RC, whichever shows the largest amplitude).

The resulting waveforms must be printed out as per the example shown in Figure 5.5.1.

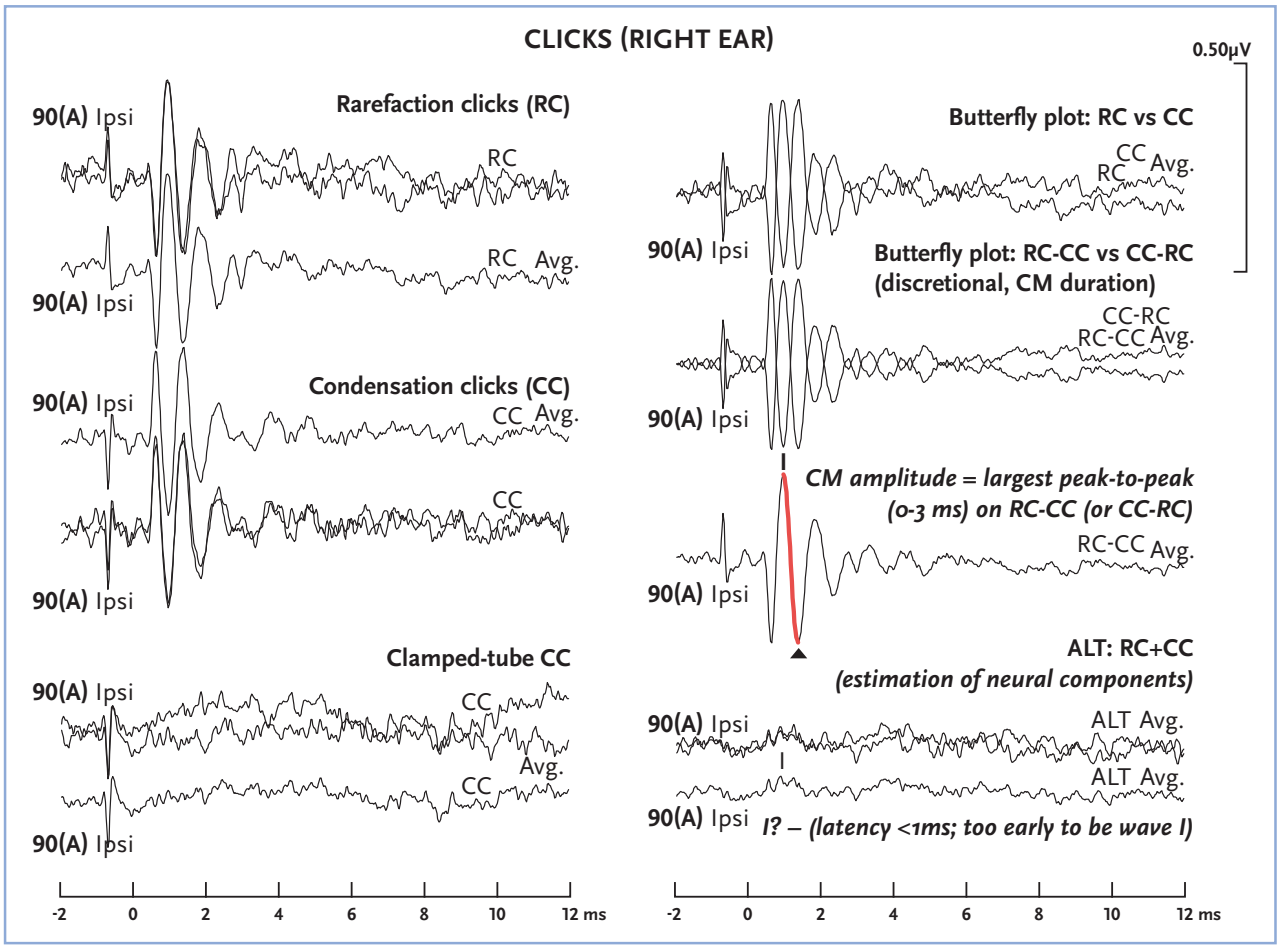


Figure 5.5.1: Display of click-ABR results required for the ANSD subprotocol. In this case, the large CM amplitude (which disappears with no-stimulus clamp) with no wave V present indicates ANSD. The butterfly plot for RC vs CC is mandatory; the second butterfly plot (RC-CC vs CC-RC) is not mandatory but may be helpful in assessing CM.

5.6 INTERPRETATION OF CM/ABR AVERAGES

Clamp-tube no-sound averages assist in distinguishing stimulus artifact from CM. The maximum peak-to-peak amplitude must be measured as CM amplitude. SP and ABR neural components are best seen in the ALT recording. ABR waves (I through V) *may* be present at any point after about 1.3 ms. Latency and amplitude of neural waveforms present must be measured. If the click-ABR shows both waves I and V, the I-V interpeak latency must be calculated and compared to age-specific normative data (Appendix ABR6).

Click stimulus artifact for each polarity is best identified using clamped-tube records. Stimulus artifact and CM are easily confused, hence the need for the clamped-tube results. Normally, the click artifact is brief, earlier than the CM and usually easy to distinguish from it. Click stimulus artifact usually ends by about 0.5 ms on properly working earphones (i.e., no excessive ringing). If stimulus artifact is very large, the EEG preamplifier may generate "ringing" due to the artifact impulse. Alternatively, as earphones "age", they may demonstrate longer-duration ringing to brief transient stimuli, especially clicks. Acoustic calibration/analyses can identify the need for new earphones by viewing the stimulus output waveform after the transducer by using a sound-level meter and an oscilloscope/laptop. In these latter cases, interpretation is more complex, thus review by a PSA is recommended.

CM is identified by displaying the averages for RC and for CC, overlaid at the first data point only (butterfly plots), and also by subtracting the RC average from the CC average (and vice versa). Polarity changing (i.e., RC and CC appear as mirror-image) CM components are revealed most clearly by the CM butterfly plot. Asymmetry of the CM with polarity is usually interpreted as the cochlear Summating Potential (SP), which may overlap with ABR wave I (if present) after about 1.3 ms.

The non-alternating physiologic components, the SP and ABR waves, are best seen in the "ALT" average (grand average calculated for RC plus CC). Comparing the RC and CC averages also reveals stimulus polarity effects on the ABR, which are not infrequent.

The CM in the butterfly plot may be of variable duration in the region from 0.5 through 3 ms. The maximum peak-to-peak amplitude must be measured using the "wave I"[9] label so that a value for amplitude and latency are provided in the data table. CM "duration" measures are not currently used by BCEHP.

ABR waves (I through V) *may* be present at any point after about 1.3 ms. They may or may not be different in the RC and CC records, both in amplitude and latency. If different, there may be partial or complete wave cancellation as well as a visual impression of phase shift in the ALT average. Additional testing, including very fast rate clicks (91.1-101.3/s rate), may be required (see "conditionally mandatory" above) in order to resolve the neural components. If a wave V is clearly identifiable, the V-V' peak-to-peak amplitude must be measured. If there is partial or total wave cancellation in the ALT (RC+CC) average relative to the RC and CC averages, the larger of the RC and CC wave V-V' amplitudes should be used.

In unilateral hearing loss, the wave V-V' in the ipsilateral channel may actually reflect that from the contralateral cochlea. Two-channel recordings, and masking, should clarify results.

If the click-ABR shows both waves I and V, the I-V interpeak latency must be calculated and compared to age-specific normative data (provided in Appendix ABR6). If prolonged more than three standard deviations from the normal mean, a retrocochlear problem (as opposed to ANSD) may be present and should be reported.

5.7 CLICK-ABR WAVEFORMS AND THRESHOLDS

Click-ABR testing may also show ABR with early ABR wave(s) but with a clear delay or absence of wave V. This pattern suggests a possible retrocochlear/neurological dysfunction that may not be typical of ANSD. If a clear wave V is seen to clicks, in contrast to waves V to tones, it may be useful to find the approximate click-ABR wave V threshold.

In order for the ANSD subprotocol to be entered, the 2 kHz tone ABR was absent or at best showed a small and/or late ABR wave V-V' complex at 80 dB nHL or higher. It would therefore be quite rare to see a normal-looking click ABR at 90 dB nHL. A much more common result would be a late and broad waveform that is presumed to be ABR wave V-V'.

Another occasional occurrence with click-ABR testing at 90 dB is an ABR waveform that shows early ABR wave(s) with a clear delay or absence of wave V. This pattern suggests a possible retrocochlear/neurological issue (such as an acoustic tumour or other brainstem dysfunction) that may not be typical of ANSD. Consultation with the BCEHP PSA is strongly recommended.

[9] The I.H.S. ABR setup does not have an option for measuring CM amplitude. In order to obtain these measures, clinicians should use the "wave I" measure, and include a note on the waveforms that this represents the CM to avoid confusion from others looking at the waveforms.

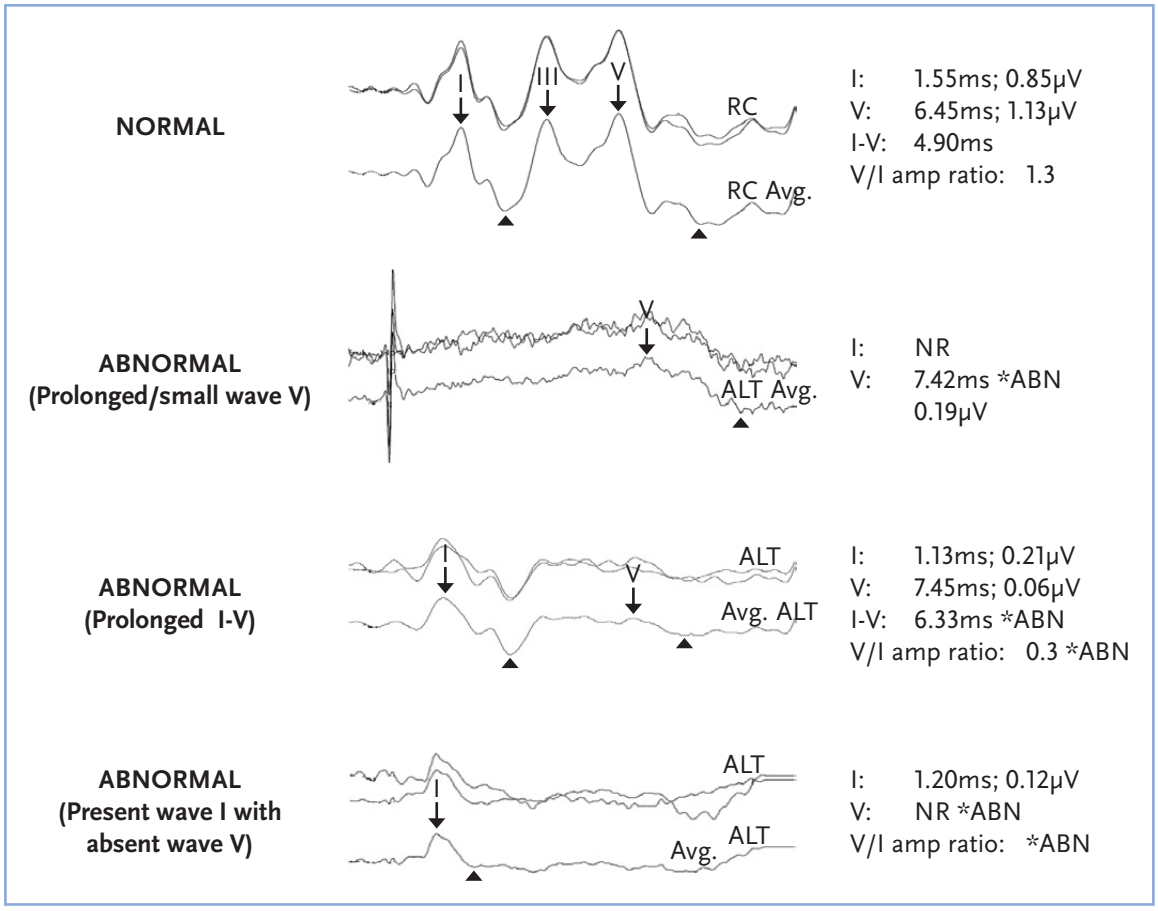


Figure 5.7.1: Click-ABR results do not always indicate ANSD; rather, they may be consistent with normal pathways, significant sensory hearing loss or mixed HL, or retrocochlear/neurological dysfunction. The first set of waveforms show normal infant click-ABR with waves I, III and V at normal latencies, indicating normal neural conduction. The second set of waveforms show only a prolonged wave V; most commonly associated with significant sensory hearing loss and/or mixed HL, and very occasionally with retrocochlear/neurological dysfunction or ANSD. The third set of waveforms show a normal wave I with a prolonged wave V. The I-V interpeak latency and V/I amplitude ratio are both abnormal, suggesting retrocochlear/neurological dysfunction. Finally, the fourth set of waveforms show infant click-ABR with only wave I present (missing wave V), suggesting a retrocochlear/neurological dysfunction beyond cranial nerve eight (CN VIII).

Tone ABRs provide information for each frequency tested, in contrast to clicks for which responses cannot be matched up to any specific frequency. Rarely, click-ABR wave V is detectable when tone ABRs are not, due either to an "island" of better hearing missed by tones or due to clicks more-rapid cochlear excitation (or combination of both). As noted, this is a rare occurrence, but if this is seen, it may be useful to track the waveform down to an approximate threshold using click stimuli. Approximate click thresholds may be useful, but interpretation of click-ABR thresholds is often very challenging and consultation with the PSA is strongly recommended. *In all cases, click-ABR "threshold" testing is discretionary; spending time on such testing must occur after all mandatory (and conditionally mandatory) procedures.*

The click-ABR threshold gives limited information about hearing sensitivity. If there is evidence of ANSD, the inference is that at least one threshold in the 0.5-8 kHz range is as good as, or better than, the click-ABR threshold and that the absence of tone responses gives no information about those thresholds. If, however, ANSD is NOT suspected, the inference from a clear click-ABR is that the tone-ABR thresholds are likely to be valid but that there may be an island of better hearing at some frequency other than those measured. If measured, the click-ABR threshold should be noted in the clinical report but not entered in the BEST frequency fields.

5.8 ROLE OF DPOAEs

DPOAEs, when present, are highly informative in relationship to ABR results; conversely, DPOAEs that are absent or questionable are not informative. The finding of DPOAEs does not eliminate the need to do the CM component of the ANSD protocol. Click-ABR is often necessary to explore the causes of abnormal ABR waveforms and CM measures usually provide additional and sometimes essential information.

DPOAEs are mandatory within the ANSD subprotocol. Normal DPOAE signal-to-noise ratios (SNRs) indicate functioning OHCs. When coupled with absent ABRs, present DPOAEs are definitive for either ANSD or, more rarely, other neuropathies that compromise action potential generation in the auditory nerve. Repeatable DPOAE presence at even a single frequency of 2, 3 or 4 kHz is incompatible with absent ABR (please see ABR Protocol Section 6.1 for DPOAE procedures and interpretation).

Repeatably absent DPOAEs at 2, 3 and 4 kHz (nominal f2 values) are consistent with ABR threshold elevation due to OHC dysfunction (assuming normal middle-ear function). If tympanograms are flat, however, absent DPOAEs have little or no value for differential identification of conventional SNHL and ANSD components.

The contribution of DPOAE testing to identification of ANSD is limited by their *reduction or absence by even minor conductive pathologies* and hearing losses. DPOAEs that are clearly present are highly informative in relationship to ABR results, whereas DPOAEs that are absent or questionable are not. For example, an absent ABR and absent OAE cannot be reliably interpreted as uniquely indicative of severe sensory hearing loss, because ANSD in combination with a minor middle-ear pathology would likely give the same results.

Normal tympanometry suggests the absence of substantial middle-ear pathology but does not rule out minor conditions that might compromise DPOAE development, so even if high-frequency tympanometry is normal, absence of DPOAEs does not guarantee major OHC dysfunction.

The finding of present DPOAEs (for at least one frequency), in practice, does not eliminate the need to do the CM component of the ANSD protocol. It is usually not appropriate to do DPOAE testing before ABR testing. Moreover, click-ABR testing is often necessary to explore the causes of abnormal ABR waveforms and CM measures usually provide additional and sometimes essential information. CM is less affected by minor middle-ear pathology than are DPOAEs. For these reasons, both DPOAE and click CM/ABR measurement are mandatory components of the ANSD subprotocol.

5.9 ROLE OF ACOUSTIC REFLEXES (ARs)

Acoustic reflex (AR) testing is discretional. Present ARs would contradict the finding of ANSD. Absent ARs add little clinical information in the presence of absent or very high threshold ABRs. ARs should be done using a BBN starting at 85 dB (not exceeding 100 dB).

Acoustic reflex testing is always discretional in ABR audiometry.

Present ARs contradict the finding of ANSD. However, if ANSD is considered definite, such as the situation of normal OAEs and absent ABR, reflex testing is not useful because even reflex presence would not carry sufficient weight to change the ANSD inference. Absent reflexes add little clinical information when tone ABRs are absent or have very high thresholds.

ARs should be done using broadband noise (BBN) starting at 85 dB (and not exceeding 100 dB). A 1 kHz probe must be used for infants up to and including 6 months corrected age and a 226 Hz probe for infants over 6 months or more (please see Section 6.3 ABR protocol).

5.10 ANSD OUTCOME CATEGORIES

ANSD component categories are "Not Suspected", "Probable" and "Definite". These categories are based mainly on comparison of sensory (DPOAE/CM) and neural (ABR V-V') measures. The larger the CM or the ratio between the CM and V-V' amplitude is, the greater the likelihood of an ANSD component.

All ANSD outcome categories except Not Suspected must be reviewed by a PSA.

World Health Organization (WHO)-aligned clinical outcome categories are Not Suspected, Probable and Definite for an ANSD component. These categories are based mainly on quantitative comparison of sensory (DPOAE/CM) and neural (ABR) measures. Key parameters are DPOAE presence/absence, CM amplitude, ABR V-V' amplitude and the CM/V-V' amplitude ratio. The larger the CM or the ratio between the CM and V-V' amplitude, the greater the likelihood of an ANSD component. The "ANSD component" terminology is used because ANSD, conventional (IHC/OHC) sensory and CHL components may be present concurrently and "sensorineural HL" does not mean simply **either** conventional sensory hearing loss **or** ANSD.

Category Determination:

Categories in Table 5.10.1 were developed by Dr. Martyn Hyde. This ANSD subprotocol and categorization scheme may also be found in the Ontario IHP Protocol (Bagatto, 2020). BCEHP and UBC are currently investigating use of these categories.

a. If DPOAEs are present at 2, 3 or 4 kHz and click ABR V-V' ≤ 0.1 µV: **Definite ANSD component**
b. If DPOAEs are present at 2, 3 or 4 kHz and click ABR V-V' 0.1 – 0.2 µV: **Probable ANSD component**
c. If DPOAEs are absent at 2, 3, and 4 kHz and CM is < 0.1 µV: **ANSD Not Suspected**
d. If DPOAEs are absent or unreliable at 2, 3 and 4 kHz, **apply table below:**

Table 5.10.1: ANSD classification (when DPOAEs are not present) based upon the relationship between CM and ABR V-V' amplitudes:

CM µV	Click ABR V-V' µV		
	< 0.1	0.1 – 0.2	> 0.2
< 0.1	*NS*	*NS*	*NS*
0.1 – 0.2	*Probable*	*See Ratio*&*	*NS*
> 0.2	*Definite*	*Probable*	*See Ratio**

NS = ANSD Not Suspected

*If CM/V-V' amplitude ratio > 1.5 = Probable ANSD component

*If CM/V-V' amplitude ratio ≤ 1.5 = ANSD not suspected

&Meeting RN requirements especially important when comparing small-amplitude waves

The ANSD component terminology is used to remind clinicians that ANSD, conventional (IHC/OHC) sensory and CHL components may be present together.

5.11 CONDUCTIVE COMPONENTS IN ANSD

If ANSD is determined to be Probable or Definite, presence of a conductive component does not change this determination. A conductive component with absent DPOAEs and small or absent ABR waves/CM makes ANSD determination unreliable; repeat ABR testing is required. If BC ABR indicates a normal ipsi/contra asymmetry, ANSD can be presumed to be absent and the ANSD subprotocol is not required.

If results indicate a Probable or Definite ANSD component, the presence of a conductive component does not change the ANSD determination. However, in the case of absent DPOAEs, small or absent CM and ABR waves, the presence of a significant conductive component, makes ANSD determination unreliable.

When entry to the ANSD subprotocol is indicated by AC 2 kHz results, the finding of a clear ABR wave V-V' in response to BC 2 kHz at 60 dB nHL or below indicates a substantial conductive component. Such a conductive component usually makes the ANSD subprotocol questionable. A CM will not be seen to a 90 dB nHL click with a mid-frequency conductive component of 20 dB or more. Also, it is almost certain that DPOAEs will be absent. Because these clues concerning the functionality of OHCs are unavailable, ANSD cannot be reliably detected or classified. Fortunately, with a BC-ABR waveform with normal ipsi/contra asymmetry, ANSD can be presumed to be absent and the ANSD subprotocol is not required.

If AC 2 kHz ABRs are absent at high levels and BC 2 kHz ABRs are also absent, a conductive component cannot be ruled out except by normal DPOAEs. If DPOAEs are absent, a flat tympanogram suggests a conductive component but does not prove it and does not quantify it. Alternatively, absent DPOAEs and a normal age-appropriate tympanogram strongly suggests absence of a substantial conductive component. The ANSD subprotocol (CM/ABR to clicks) is indicated in both cases and may prove informative.

If a substantial conductive component cannot be ruled out, ANSD is unlikely to be reliably assessed and a conventional sensory component may be overestimated. The overall interpretation will default to a severe or profound sensorineural hearing loss with a possible conductive component and ANSD could not be assessed. Repeat ABR will likely be required following ENT consultation and/or medical management of transient middle ear pathology.

Waiting until VRA is obtained before referral to BCEHP intervention services is not acceptable, given the low probability of ANSD relative to that of severe/profound SNHL.

5.12 PSA CONSULTS AND ADDITIONAL TESTS

For all cases for which ANSD is considered Probable or Definite, the PSA(s) must be consulted and referral made via BEST for further testing at BCCH.

For all cases for which ANSD is considered Probable or Definite, the PSA(s) must be consulted and referral made via BEST for further testing at BCCH. This allows for early and timely ENT consult, MRI and slow CAEP testing (usually at age 4 months), as deemed appropriate. Moreover, if there are challenges disentangling sensory and neural components or in determining the ANSD outcome category, consultation with a PSA is strongly required. Additional testing may be specified, to be done either by the referring ABR Audiologist or by the PSA. Such testing may include very high stimulus rates and additional manipulations of averages, to clarify interpretation of records.

5.13 ANSD EARLY MANAGEMENT

For children where ANSD is considered Definite or Probable, subsequent CAEP testing at age 4 months, and VRA behavioural testing at about 6-9 months of age, will potentially clarify thresholds and inform interventions. There is variability regarding management in the literature with regard to amplification and/or cochlear implants. Fluctuating hearing is an occasional finding but is not typical. Careful communication with caregivers in regard to the ABR test results, hearing issues related to ANSD, and future testing and intervention is imperative.

Through BCEHP, ANSD is often determined to be present by age 2 months (corrected age). In babies whose newborn hearing screening was carried out using OAEs, ANSD may not be identified for several years. In most cases with ANSD, more than one ABR audiometry session will likely be required to correctly identify ANSD and determine any ABR thresholds.

For Probable or Definite ANSD, tone and click ABR thresholds are either indeterminate or may overestimate true thresholds; nevertheless, they can still give useful upper bounds for perceptual thresholds. Subsequent testing will include slow CAEP testing at age 4 months, and VRA behavioural testing at about 6-9 months of age, to clarify thresholds and inform interventions. Based upon BCEHP experience and results in the literature, CAEP testing in children with ANSD may require multiple test sessions and does not always provide useable results. For example, a review by Gardner-Berry and colleagues indicates about only about 50% of children with ANSD will show a CAEP response near behavioural threshold, and even for stimuli well above (> 20dB) behavioural threshold, only 35%-82% show a CAEP response (Gardner-Berry et al., 2016). This contrasts with CAEP results for children without ANSD (with or without hearing loss) where CAEPs have been shown to provide reasonably accurate threshold estimates (Cone & Whitaker, 2013; Van Dun et al., 2012). Nonetheless, the literature shows that CAEP testing can provide useful information for some children with ANSD. For example, CAEP results sometimes show that hearing thresholds are better than those indicated by ABR or VRA. At the time of writing this protocol (November 2022), CAEP testing may be used to determine if thresholds may be better than ABR and VRA. **NOTE:** BCEHP does not currently use CAEP thresholds in isolation to make recommendations in regard to amplification.

Hearing loss and speech perception deficits vary widely in ANSD. Most affected children experience significant speech perception deficits in noise. There is variability in the literature, with amplification and use of FM systems being beneficial in some cases, whereas cochlear implants are beneficial in others.

Careful communication with caregivers is required if the ANSD test outcome category is Probable or Definite. ANSD is not easy to explain, especially its relationship to "conventional" hearing loss, the consequent inaccuracy of the ABR and any waiting period prior to decision-making about interventions. Other issues include the variable quality of information about ANSD available on the internet, as well as the number of misconceptions that exist about the disorder, even across hearing health professionals.

Some basic, key points to be explained for families are:

- When ANSD is present, behavioural/functional hearing levels might be better than that indicated by the ABR test.
- Infants with ANSD have a wide range of hearing losses, but most have some degree of loss.
- Behavioural hearing testing usually will be tried at about 6-9 months of age.
- Family observations of response to sounds may give useful information.
- All Probable or Definite ANSD cases should have immediate referral to BCEHP Service Coordination.

- Many children with ANSD have difficulty understanding speech, especially if there is a lot of background noise or other people talking.
- The extra difficulty understanding speech happens because ANSD interferes with the timing of sound signals as they travel up the hearing nerves to the brain.
- Some children with ANSD will benefit from amplification.
- Some children with ANSD who do not get much benefit from amplification may do well with cochlear implants.
- There is information about ANSD available from the Internet that is incomplete or invalid.

See Roush et al. (2011) for a comprehensive review of audiologic management of children with ANSD. See Teagle et al. (2010) on cochlear implants in ANSD. A BCEHP brochure and video explaining the basics of ANSD in lay language for caregivers is available.

It is often quoted and written that fluctuation of hearing and possible improvement in hearing over time are common occurrences with ANSD, or even key characteristics of it. These statements are incorrect. Fluctuation of hearing levels in ANSD is not a common finding and is probably confined to specialized sub-types of ANSD. Similarly, while it is possible that hearing levels may change over time in a few cases, the actual incidence of progression or improvement is not well understood and may be very low. The evidence to date for improvement in hearing levels is not of high quality; it should be evaluated critically in relation to individual candidacy for interventions such as cochlear implants.

5.14 ANSD FIELD ENTRY IN THE BCEHP BEST DATABASE

Enter the diagnosis of ANSD in the BEST database.

The BEST data system allows the clinician to put in the diagnosis of ANSD for Permanent Hearing Loss or Uncertain Diagnosis. Hearing threshold estimates in dB nHL should be entered, even though they are likely to be biased. The BEST system currently does not allow for classification of ANSD as Probable or Definite.

5.15 POST-ABR REFERRALS

For all cases where ANSD is considered Probable or Definite, children should be referred to BCCH for further testing and to BCEHP Service Coordination for intervention services.

All Probable or Definite ANSD cases should have immediate referral to BCEHP Service Coordination. As noted in Section 5.12, all Probable or Definite ANSD cases will be referred to BCCH for further testing (including slow CAEPs), as well as ENT, after review by PSA.

6 ANCILLARY PROCEDURES

6.1 DISTORTION PRODUCT OTOACOUSTIC EMISSION (DPOAE) TESTING

DPOAEs are mandatory when permanent hearing loss has been identified and as part of the ANSD subprotocol. In other scenarios they are discretional (i.e., when ABR shows CHL or normal hearing). A copy of the DPOAE results must be retained on file.

Mandatory when permanent hearing loss has been identified, DPOAE interpretation considers DPOAE amplitude, SNR and noise-floor levels at each frequency tested and now follows the method recommended by Gorga and colleagues (Gorga et al., 1993, 1997). These norms were originally collected on a range of subjects with normal hearing and hearing loss (Gorga et al., 1993, 1997). They have been validated on large samples of infants and young children since this time (Gorga et al., 2000). In addition, more recent research (Blankenship et al., 2018; Hunter et al., 2018), also collected from infants and children across different ages, found similar ranges of values to Gorga et al. showing good convergent validity.

EQUIPMENT AND DISPLAY

A DPOAE system that satisfies the protocol collection parameters listed in this protocol must be used. DPOAEs must be measured at nominal (f2) frequencies of 2, 3, 4 and, where feasible 6 and 8 kHz, in descending frequency order. Clinicians may wish to test lower frequencies if time and ambient noise levels permit. The f2/f1 ratio is 1.2, with f1 and f2 levels of 65 and 55 dB SPL. Protocol collection parameters are shown in Figure 6.1.1 below. To interpret results, stimulus levels, DPOAE amplitude and noise-floor levels at each frequency tested must be measured and not only a pass or fail result that is common in screening OAE applications. If replications are obtained, they should be superimposed. Left and right ear traces should be plotted side by side. The related numerical values (often displayed in a table) provided by the software are also required.

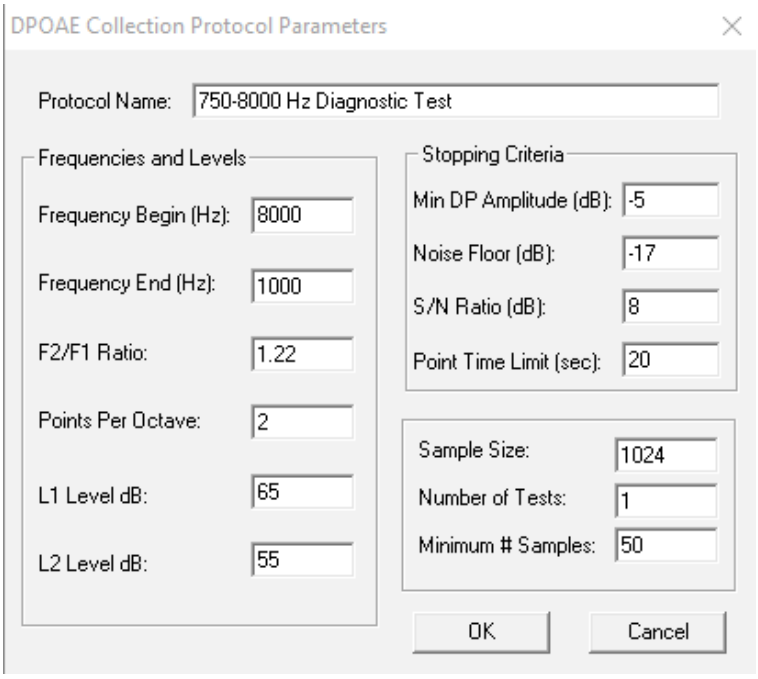


Figure 6.1.1: DPOAE Collection Protocol Parameters.

TEST CONDITIONS

Clinical OAE assessment should be completed in a quiet space or audiometric test booth and be free of continuous background noise. The ear canals should be free of debris or cerumen based on visual inspection with otoscopy. Good probe fit is essential; the largest tip size that can comfortably be accommodated by the child's ear should be selected and the probe should be fully inserted into the ear canal. Probes must be checked regularly for sound output and microphone sensitivity (once per week is recommended). Annual calibration is required.

PROCEDURE AND INTERPRETATION

As stated previously, DPOAES must be measured using nominal f2 frequencies of 2, 3, 4 and, where feasible, 6 and 8 kHz, in descending frequency order. Interpretation considers the DPOAE amplitude, SNR and noise-floor levels at each frequency tested and is based on the normative data from Gorga et al. (1993), shown in Figure 6.1.2, which shows the 10th percentile for Distortion Product (DP) levels for people with normal hearing (lower boundary of the Borderline Range) and the 90th percentile for DP levels for people with hearing loss (upper boundary of the Borderline Range). Figure 6.1.2 shows DP levels (in dB SPL) that fall within three normative ranges: Normal (N), Borderline (B) and Hearing Loss (R). Table 6.1.1 provides the actual dB SPL values to be used by ABR Audiologists to determine which of the three above normative ranges a DP dB SPL falls into: (i) DP levels that are above the upper boundary are "Normal" (line 1); (ii) DP levels that are below the lower boundary are "Abnormal/Hearing Loss" (line 2); (iii) DP levels falling between (or equal to) the upper and lower boundaries are in the "Borderline" range.

Interpretation of the above DP levels, however, requires consideration of the SNR levels, as described by Gorga and colleagues (1993) and outlined in Table 6.1.2. DP levels that fall in the Normal (N) range *and* have an SNR of 6 dB or greater are considered to be "Present". DP levels that fall in the Hearing loss (R) range, regardless of SNR, are reported as "Absent". Anything that does not meet the criteria above must be interpreted as Could Not Determine/Noisy (see Table 6.1.2 for interpretation outcomes).

If an SNR of 6 dB is not achieved and the level of the noise floor at any frequency is higher than the lower limit/line of the Borderline range (see Row 2 in Table 6.1 for specific values), results must be judged to be "Noisy" (i.e., one cannot conclude "Absent" in this case as the high noise floor may have prevented a sufficient SNR from being achieved). Noise from the child and environment is highest at frequencies lower than 2 kHz; testing below this frequency should be terminated if noise levels do not permit OAE levels consistent with the distribution of ears with hearing loss by Gorga et al. (1993).

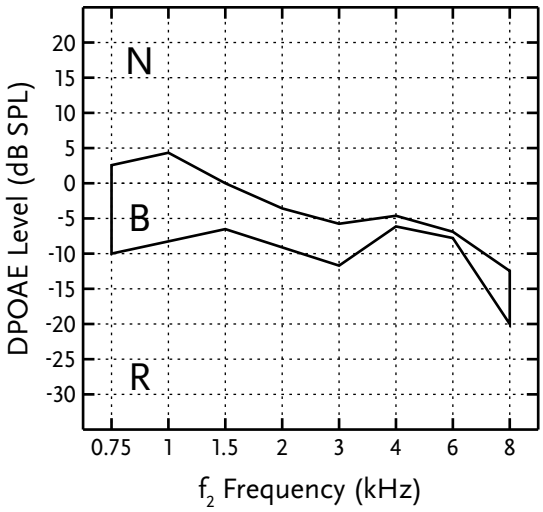


Figure 6.1.2: DP levels will either fall in the Normal (N) range, Borderline (B) range or Hearing Loss (R) range. The interpretation of the results depends both on the SNR and noise-floor measurement. There are 3 possible outcomes when the SNR is > 6. A DPOAE for a given frequency is considered "Present" if it falls in the "Normal" range and has an SNR > 6. If the SNR is > 6 but the DPOAE level falls within the "Borderline" or "Hearing Loss" range, the interpretation must be Could Not Determine or Absent, respectively. Three possible outcomes are also possible when the SNR falls below 6dB. If the SNR is below 6 and the DPOAE levels falls in the "Borderline" or "Normal" range, the interpretation must be "Noisy". Only when the DPOAE levels falls in the "Hearing Loss" range with SNR less than 6 can a response be determined Absent. This information is also displayed in Table 6.1.2 (Gorga et al., 1993)

Table 6.1.1: DP levels (dB SPL) associated with upper and lower boundaries of the borderline range on the DP-gram

	DP Frequency (Hz)							
	750	1000	1500	2000	3000	4000	6000	8000
Upper Bound	3	4	1	-4	-6	-5	-7	-12
Lower Bound	-10	-7	-6	-10	-11	-6	-8	-20

Note that for determining response absence, testing should be terminated once the noise floor at a specific test frequency falls below the lower limit of the Borderline range at that frequency (Row 2 lower bound). While manually advancing testing when it meets specific criteria is possible, automatic stopping rules to advance testing to another frequency based on the SNR, minimum number of trials, etc. are available on many DPOAE machines (e.g., Biologic/Natus Scout and Interacoustics Titan). A minimum of 10 trials must be obtained at each frequency tested.

Table 6.1.2: DPOAE interpretation of SNR and DP Level combinations

SNR	DP Level	Interpretation
≥ 6 dB	Normal area	Present
≥ 6 dB	Borderline area	Could not be determined
≥ 6 dB	Refer area	Absent
< 6 dB	Normal area	Noisy
< 6 dB	Borderline area	Noisy
< 6 dB	Refer area	Absent

Table 6.1.2 describes the interpretation scenarios for DPOAE response. Clinical results for DPOAE findings should be reported for the specific frequencies where DPOAEs were present, abnormal or could not be determined rather than the overall Pass or Refer/Fail descriptors used to report the results of OAE screening.

CLINICAL IMPLICATIONS

DPOAE presence suggests grossly normal functioning of the middle ear and the cochlear OHCs at a specific frequency. Significant conductive disorders are ruled out. Cochlear hearing loss greater than 40 dB HL is unlikely. Present DPOAEs and absent ABR are definitive for auditory neuropathy spectrum disorder (ANSD).

Unfortunately, many factors other than cochlear hearing loss can affect DPOAEs. These include a noisy environment, active baby, inadequate probe placement, eartip blockage and an array of middle ear conditions. As a result, the absence or marked reduction of DPOAEs carries little clinical information without additional information from immittance, electrophysiology or behavioral hearing assessments.

A copy of all DPOAE results must be retained in the clinical chart.

6.2 MIDDLE-EAR ANALYSIS: TYMPANOMETRY

> Tympanometry is mandatory if hearing loss has been confirmed by ABR audiometry. Tympanometry will be completed with a 1 kHz probe frequency for infants under 6 months corrected age and with a 226 Hz probe for infants aged 6 months or more. Tympanograms will be plotted and retained on file.

Tympanometry is mandatory if hearing loss has been confirmed by ABR audiometry. Tympanometry criteria are set at the 5th percentiles of age-specific normative distributions. In the case of double peaks, the larger peak is used. Admittance change without development of a genuine peak is abnormal regardless of change size. Caution is required in applying these criteria to young neonates, in whom canal wall collapse may lead to steep negative tails.

The clinical utility of other measures such as peak pressure, width and gradient is unclear in infants. Reported 90% range boundaries for tympanometric peak pressure (TPP) are from approximately (-150 to -100) up to (0 to 50) daPa.

INFANTS UP TO AND INCLUDING SIX MONTHS CORRECTED AGE

Tympanometry must be done using a 1 kHz probe frequency, with repetition if the tracing is noisy or if it is not clearly normal. The key abnormality criterion is a compensated peak static admittance of ≤ 0.6 mmho, compensated from the negative tail at -400 daPa.

INFANTS OVER SIX MONTHS CORRECTED AGE

Tympanometry must be done using a 226 Hz probe frequency, with repetition if the tracing is noisy or if it is not clearly normal. The key abnormality criterion in the age range 7-12 months is a compensated peak static admittance of 0.1 mmho, compensated from the positive tail at +200 daPa. From 13-18 months, the criterion is 0.15 mmho. From 19 months on, the criterion is 0.2 mmho.

A copy of all tympanometry results must be retained in the clinical chart.

6.3 MIDDLE-EAR ANALYSIS: ACOUSTIC REFLEXES

Acoustic reflex (AR) measurement is always discretional but may be clinically contributory as a crosscheck in the context of suspected ANSD. If ipsilateral ARs are elected to be done, a 1 kHz probe must be used for infants up to and including 6 months corrected age and a 226 Hz probe for infants over 6 months or more. The eliciting stimulus may be a 1 kHz tone or broadband noise (BBN). ARs will be retained on file, if completed.

Acoustic reflex (AR) measurement is always discretional but may be clinically contributory as a crosscheck in the context of suspected ANSD. When an ANSD component is actually present, a clear AR is an unusual finding that should lead to careful re-evaluation of any evidence for inference of an ANSD component. AR presence also has some clinical value as a crude crosscheck when AC-ABR thresholds are poorly defined and suggest hearing levels over about 80 dB eHL. If such situations occur, then the reliability of the ABR threshold should be re-examined and possible causes of poor threshold definition should be identified and remedied.

If ipsilateral ARs are elected to be done, a 1 kHz probe must be used for infants up to and including 6 months corrected age and a 226 Hz probe for infants over 6 months or more. The eliciting stimulus may be a 1 kHz tone or broadband noise (BBN), the latter being the preferred stimulus because it is usually more effective than tonal stimuli for reflex elicitation.

The goal is not to establish an accurate reflex threshold, but to show presence or absence of reflexes at an appropriate stimulus level. Reflex presence is usually defined by a repeatable, clear, negative deflection, though biphasic and even positive deflections sometimes occur.

It is the reproducibility of the elicited waveform, not its precise morphology, that is the primary factor in response identification.

The starting level should be 85 dB SPL. In infants under 6 months of age, the maximum nominal level must not exceed 100 dB, because of the SPL variability across young infants due to differences in canal volume and geometry. For older infants, very small canals are uncommon and the maximum nominal stimulus level is discretional.

Printout is mandatory if the AR is given substantive clinical weight in overall interpretation of test findings.

6.4 REAL-EAR-TO-COUPLER DIFFERENCE (RECD) MEASUREMENT

RECDs are discretional during ABR audiometry. However, they have obvious value when PHL has been identified and in a context of imminent amplification fitting. They also have value in longitudinal threshold comparisons that may be affected by anatomical changes in individual ears with increasing age, for example in avoiding false-positive inference of hearing loss progression. If feasible, obtain RECDs as part of the ABR audiometry session, after all mandatory components have been completed. Otherwise, RECDs will be completed by the fitting audiologist. See the BCEHP Amplification Protocol for additional information.

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APPENDICES

APPENDIX ABR1 – ABR RECORDING SHEET

BC Early Hearing Program

A service of BC Children's Hospital
and the Provincial Health Services Authority

ABR RECORDING SHEET

Page ___ of ___

Patient Name: _____ **DOB:** _____

Age at ABR (corrected): _____ **Test Date:** _____

Tester(s): _____ **BCEHP#:** _____

EQUIPMENT: Intelligent Hearing Systems SmartEP **IMPEDANCE:** ☐ ≤3kOhms (if not, provide details)

FILENAME Time Start Recording: Both ear inserts: ☐ Y ☐ N [1]	**EAR** **R/L**	**INTEN** (dBnHL)	**STIM**		**CHAN*** (if BC; I/C)	**SNR***	**RN*** (μV)	**Overall RP ✓ NR × or CNE**	**COMMENTS** Patient State: Quiet/Noisy/Asleep etc.
			AC BC	**FREQ RC or CC**					
Time Stop Recording:									

KEY: AC: air conduction; BC: bone conduction; RC: rarefaction click; CC: condensation click; ALT: alternating polarity; ✓: response present; ×: response absent; CNE: could not evaluate; RN: residual noise; SNR: signal-to-noise ratio

NOTE: To determine no response (NR): RN must be ≤0.08 μV for combined (added) waves [≤0.04 μV for combined (added) waves that are non-flat]; SNR≥1.0: likely response (however, replications required to determine threshold); Smart-EP "SNR Region" must be set correctly (10-ms wide window) for recordings and for offline "additions" using exact windows specified by setup files;

* Recommended but not mandatory to record these values on this sheet.
[1] If not, add in comments what the circumstances were that prevented both inserts from being placed simultaneously.

APPENDIX ABR2 – INTELLIGENT HEARING SYSTEMS (IHS) ABR DATA BACKUP

ABR Data obtained using the IHS system needs to be manually backed up using the following procedure once every 6 months.

BACKUP ABR DATA USING THE IHS GENERAL DATA BACK UP UTILITY

- Open the Intelligent Hearing Systems (IHS) application.
- In the **Patient** menu, select the **General Data Backup Utility**.
- In the General Data Backup Utility, select the checkbox next to the option **Select All NOT Backed Up.**
- Click on the **Select Destination Directory**. Create a new folder and rename it using the following format: IHS-Site Code Date (e.g. IHS-104 2018-10-05). Click **Save** to confirm the new folder as the backup directory.
- Click on **Backup Selected Data** to begin back up process.
- Once the back-up process is complete, each entry will be marked as Backed Up along with the date and destination directory.

TRANSFER BACKED UP ABR DATA TO NETWORK FOLDER

- Insert a hardware encrypted USB drive into the IHS laptop (e.g., Kingston DataTraveler Locker).
- Enter the USB drive's password into the Password Utility to unlock the drive.
- Open Windows Explorer and locate the folder created in Step 4 (back up designation directory).
- Right click on the folder and select **Send To** > **Compressed (zipped) folder**.
- Copy and paste the newly created compressed (zipped) folder into the USB drive.
- Remove the USB drive by shutting down the USB drive's Password Utility.
- Insert the USB drive into a PHSA-issued computer connected to a Health Authority's network.
- Enter the USB drive's password into the Password Utility to unlock the drive.
- Open Windows Explorer and locate the compressed (zipped) folder on the USB drive.
- Copy and paste the zipped folder into the network folder where ABR data should be backed up to.
- Once the data has been backed up to the network folder, delete the copy saved on the USB drive.
- Remove the USB drive by shutting down the USB drive's Password Utility.

DELETE BACKED UP ABR DATA

- On the IHS laptop, open the **General Data Backup Utility**.
- Select **Delete Backed Up Data**.
- Enter the password for the IHS system.
- Click **Ok** to confirm you want to permanently delete the backed up data.
- Open Windows Explorer and delete both the backup folder created in Step 4 and the compressed (zipped) folder created in Step 10.

APPENDIX ABR3 – ABR TECHNICAL DETAILS

ABR IHS SMARTEP CALIB FILE OFFSETS FOR BCEHP: NOMINAL 0 DB NHL AT DIAL 0 DB

These values are numbers specified by BCEHP in the EP Utilities/EPSetUP/Calib file that are intended to produce appropriate stimulus levels, such that dial values approximate dB nHL values. These numbers apply to the Intelligent Hearing Systems SmartEP system ONLY, as this is the required instrumentation for evoked potentials within BCEHP.

It should be noted that simply entering the number as listed below into the IHS SmartEP parameters does NOT ensure actual SPL (or force level for BC) will be correct due to transducer differences and especially transducer changes (due to age, overuse, damage, etc.). Calibration (at least annual) is required to ensure appropriate levels are generated by the transducers.

STIMULUS TRANSDUCERS

Air Conduction: insert earphones (ER-3A) except where specifically contraindicated, in which case supra-aural earphones (TDH/MX41 type) are optional.

Bone Conduction: bone vibrator as specified by ANSI S3.6-1996, held in place by hand or custom velcro band.

Air Conduction (in dB SPL) from Small & Stapells 2017

Frequency	TDH49	ER3A
	dBppeSPL	dBppeSPL
0.5 kHz	25 dB ppe	22 dB ppe
1 kHz	23 dB ppe	25 dB ppe
2 kHz	26 dB ppe	20 dB ppe
4 kHz	29 dB ppe	26 dB ppe
Clicks	36 dB peak	31 dB peak

BONE CONDUCTION (IN DB RE 1µN) FROM SMALL & STAPELLS 2017

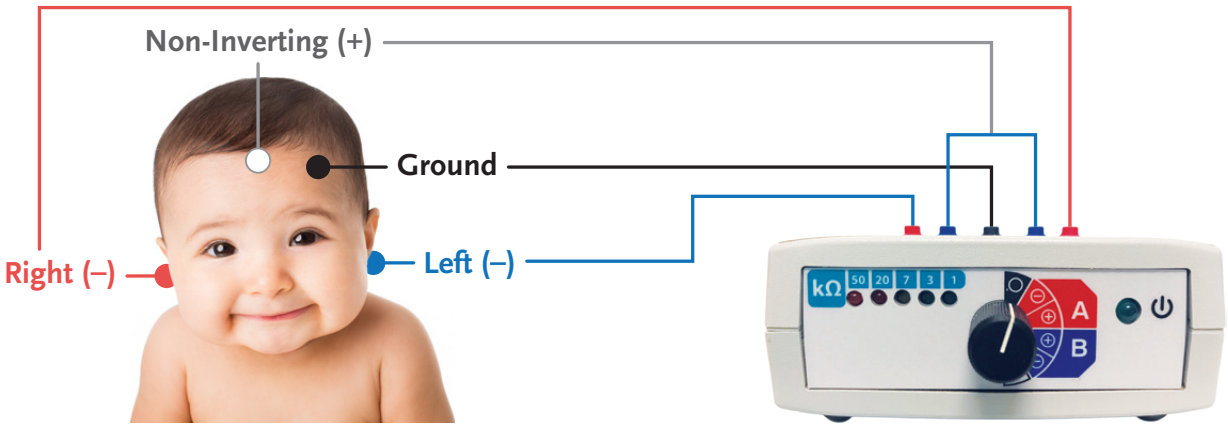
Frequency	B71
	dB Force
0.5 kHz	67 dB ppe
1 kHz	54 dB ppe
2 kHz	49 dB ppe
4 kHz	46 dB ppe
Clicks	51 dB peak *(from Richter & Fedtke, 2005)*

PROTOCOL FILES

As distributed by BCEHP

ELECTRODE SITES

Electrode Configuration
2-Channel Differential Opti-Amp Transmitter



Electrode Sites	Connection to 2-Channel Opti-Amp Transmitter
Non-inverting electrode (grey): High midline forehead, referenced to:	Connects to the **Y-ADAPTOR**
Inverting Channel 1: RIGHT low mastoid electrode (red lead)	Connects to the **RED transmitter plug (A)**
Inverting Channel 2: LEFT low mastoid electrode (blue lead)	Connects to the **RED transmitter plug (B)**
Common/ground electrode (black lead): Lateral forehead >3cm from non-inverting	Connects to the **BLACK transmitter plug**

ELECTRODE IMPEDANCE

≤ 3 kOhms for all electrodes

Difference between electrodes within a channel of ≤ 1 kOhm

CHANNELS

Air Conduction:	View Ipsi or Both, Plot Ipsi
Bone Conduction:	View & plot Ipsi AND Contra

FILTERS

High-pass (Low)	Tone pip thresholds	30 Hz
	All click recordings	30 Hz
Low-pass (High)	Tone pip thresholds	1500 Hz
	All click recordings	3000 Hz
Notch filter	Off	

ARTIFACT REJECT

On, typically +/-10 µV

AMPLIFIER GAIN

100,000

AVERAGING

1000-2000 accepted sweeps per average, typically 2 to 4 averages per condition.

See residual noise levels.

SNR/RN/CORRELATION (CCR) TIME REGIONS

Stimulus	RN, SNR & Correlation (CCR) Window
Clicks	1.8 – 11.8 ms
AC 0.5 kHz tones	10.5 – 20.5 ms
BC 0.5 kHz tones	20 dB nHL: 10.5 – 20.5 ms 30-50 dB nHL: 14 – 24 ms (only RN valid) **NOTE:** higher BC is later because of stimulus artifact
AC 1 kHz tones	7.5 – 17.5 ms
AC/BC 2 kHz tones	6.5 – 16.5 ms
AC/BC 4 kHz tones	5 – 15 ms

SNR CRITERION

- If the SNR is **greater than or equal to 1.0** then a response is likely present.
- Sometimes response is visually present with an SNR lower than 1.0.
- Visual determination of RP is currently the preferred method.

ONLINE RESIDUAL NOISE CRITERIA

To determine NR for a given set of waveforms, the RN must be less than or equal to

- **0.08** µV in the grand average waveform (composite average of all replications)
- **0.04** µV in the grand average if the waveforms are not entirely flat
- *even if RN meets criteria, waveforms must be visually flat (and with no clear wave V) at a reasonable display scale (e.g., 0.5 µV and 25% plot size)*

EPOCH LENGTH

23-25 ms for tone pips (25.6 ms on IHS SmartEP)

12-15 ms for clicks (12.8 ms on IHS SmartEP)

ANALYSIS OFFSET

Zero ms for tone pips

-2 ms for clicks

VISUAL DISPLAY SCALE

Tones: Typically, 0.5µV and 25% plot size

Clicks: Typically, 0.5-1.0µV and 25% plot size

STIMULUS PARAMETERS

Tone pips: Linear ramp (Trapezoidal envelope), 2-1-2 cycle rise/plateau/fall times; or 5-cycle exact-Blackman window (no plateau): Alternating polarity; Repetition rate ~39.1/s.

Clicks: 100-µs pulse duration; recordings to single polarity condensation and rarefaction polarity as specified (i.e., do not use "alternating" polarity); Repetition rate 19.1/s. Higher rates (91.1-101.3/s) may aid identification of wave V.

MASKING

Ipsilateral: None

Contralateral: Discretional

APPENDIX ABR4 – ABR ACOUSTIC CALIBRATION

PREFACE

IMPORTANT NOTE RE: ABR CALIBRATION

The following section must be read and understood by any equipment calibration specialist prior to undertaking any ABR calibration for BCEHP. All ABR systems used by BCEHP are used within special guidelines which include specific calibration details. These details must be adhered to without modification, unless specific permission is granted by BCEHP. As the actual calibration levels have been locally researched and generated for use within the provincial health system, the various offsets may differ from those used in other areas or as recommended by various manufacturers of ABR equipment. Do not use manufacturer guidelines or other "standards" to calibrate ABR systems within the province of B.C. (or within any similar program trying to duplicate the B.C. standard or results).

Specific Details:

Coupler: As the DB0138 (equivalent to HA2) 2-cc coupler has been used to generate the specific numbers used in the program, only this coupler should be used for measuring insert output. While it is arguable that IEC couplers can be used with corrections, they will not be accepted on the grounds that it will almost certainly lead to confusion over time. The required DB0138 (HA2) coupler is available from Bruel & Kjaer and G.R.A.S.

Bone vibrator measurement: *Only the B&K 4930 artificial mastoid* will be accepted for use as a transducer for measuring bone vibrator energy. The equipment calibration specialist must show proficiency in calculating how to measure bone vibrator levels in dB (re: 1 µN) for any specific artificial mastoid used. The documentation for this is provided by the artificial mastoid manufacturer upon purchase and also upon calibration. The documentation and calculations may be requested by the owner of the equipment used for calibration.

Mandatory procedures to note:

- The output for each stimulus used for ABR testing can be accessed and individually adjusted in a special calibration mode as outlined in Part 1.
- In "calibration mode", the output is measured as a continuous tone which can be read using the RMS function of the sound level meter. The Smart-EP system provides two methods to calibrate stimuli; BCEHP normally uses the "HL" mode (where the SPL-to-nHL offset is added to output for measurement).
- If requested, click stimuli must be calibrated using the peak hold function of the sound level meter.
- It is not permissible to modify or adjust any numbers in the SPL-to-HL table.

MOST IMPORTANTLY!

If any ABR system under calibration is currently in service by an equipment calibration specialist, and a reading which requires a large change (more than 2.5 dB) is obtained, calibration should be stopped and the process reviewed. It is highly unlikely that an error of more than 2.5 dB will exist, especially for insert earphones; either the earphone has been damaged or the calibration specialist has made an error. Any larger errors found should be reported to the PSA(s) via the ABR support email and a description provided in the comments section of the ABR calibration record (attached at the end of this appendix). Additionally, it may be helpful to compare findings from the system being calibrated to those of other systems before changes are made. Inaccurate results following a calibration session are extremely disruptive to the program and the families involved and may cast doubt on the service vendor and ABR test results across the province.

INTRODUCTION

This calibration appendix is intended to provide detailed instructions for Auditory Brainstem Response (ABR) calibration for equipment calibration specialists and ABR Audiologists. **The information provided is specific to the calibration of air- and bone-conducted (ABR) stimuli using BCEHP targets and the Intelligent Hearing Systems (IHS) SmartEP system required by BCEHP. It is required by BCEHP that the DB0138 (HA2) 2-cc coupler be used for air-conduction calibration; the IEC711 ear simulator is not to be used for BCEHP calibrations. The use of a B&K artificial mastoid is required for bone-conduction calibration.** There are several different sets of calibration targets used by Early Hearing Detection and Intervention programs in the world and different calibration couplers/devices used by calibration companies, so it is critical to be familiar with **required BCEHP-specific targets and equipment** to know how IHS ABR systems are calibrated for our program (USB Box & Duet systems use the same calibration method). In addition to verifying the output of transducers (i.e., meeting calibration targets), it is also important to confirm the integrity of the stimulus presented (e.g., check earphone output for ringing).

The following appendix is divided into three parts: Part 1: Calibration Information specific to BCEHP, Part 2: Calibration Information Specific to IHS System and Part 3: Verification of integrity of stimulus. ABR Audiologists should be familiar with all sections but will most often be verifying that the correct BCEHP targets are listed in the calibration modules within the IHS software.

PART 1: CALIBRATION INFORMATION SPECIFIC TO BCEHP

To verify that your IHS system is using the correct calibration values for BCEHP, open the SmartEP module in the Launch Pad software and click on the "Stim:" tab in the bottom right corner of the SmartEP control panel, as shown in the background of Figure 1A and 1B. The "Auditory Stimulus Generation" window will open (Figure 1A). You can check that the correct SLP-to-HL[10] offset targets (henceforth called "BCEHP calibration offset targets") are entered for each transducer type selected by clicking on the "SPL to HL Table" tab in the right corner of Figure 1A; this opens the "SPL to HL Conversion Table" (Figure 1B). The values in the SPL to HL Conversion Table must correspond to the BCEHP calibration offset targets for the transducer type selected on the right side (Hatton et al., 2012; Small & Stapells, 2003; Small & Stapells, 2017; Stapells, 2000). These values are also entered on the "BCEHP I.H.S. SmartEP Calibration for ABR" form used for routine annual calibration record keeping shown at the end of this appendix.

Be sure that you have selected the transducer type of interest in Figure 1B each time you want to verify that the SPL to HL conversion values are correct. Figures 2, 3 and 4 show the correct BCEHP "Conversion values in dB" for ER3 insert earphones, supra-aural headphones and the B-71 bone vibrator, respectively.

NOTE: *BCEHP-ABR audiometry requires that "BCEHP calibration offset targets" be used, NOT those provided by the manufacturer or any other calibration target in the literature. The published SPL-to-HL calibration offsets used by BCEHP (Hatton et al., 2012; Small & Stapells, 2003; Small & Stapells, 2017; Stapells, 2000) are only available for 0.5, 1, 2 and 4 kHz for air- and bone-conducted stimuli, as highlighted by the green boxes (Figures 2, 3 and 4). Additionally, SPL-to-HL calibration offsets for 6000-Hz air-conducted stimuli (for insert earphones, Figure 2) have been estimated, based on the literature, and are provisional. These research-based "BCEHP calibration offset targets" must be entered in the "SPL to HL Conversion Table" and must NEVER be changed. It is important that the equipment calibration specialist confirm these offsets after each calibration, especially following software updates.*

[10] Note that the conversion factors are actually "peSPL to nHL"; however, to be consistent we are using the same terminology that is used by the I.H.S. software

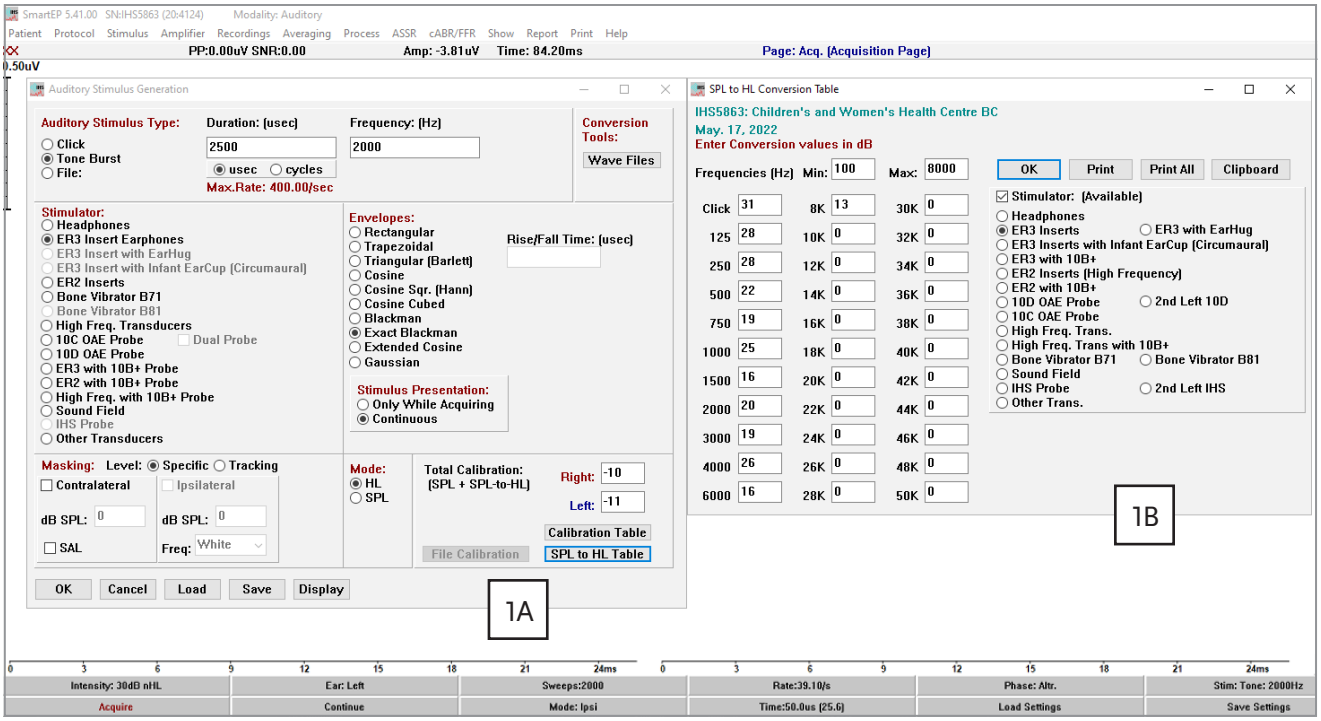


Figure 1A & 1B: IHS SmartEP calibration windows that are viewed to verify that BCEHP calibration offset targets are correctly applied (Hatton et al., 2012; Small & Stapells, 2003; Small & Stapells, 2017; Stapells, 2000). (1A) "Auditory Stimulus Generation" window and (1B) "SPL to HL Conversion Table". The screen behind these tabs is the main SmartEP user window.

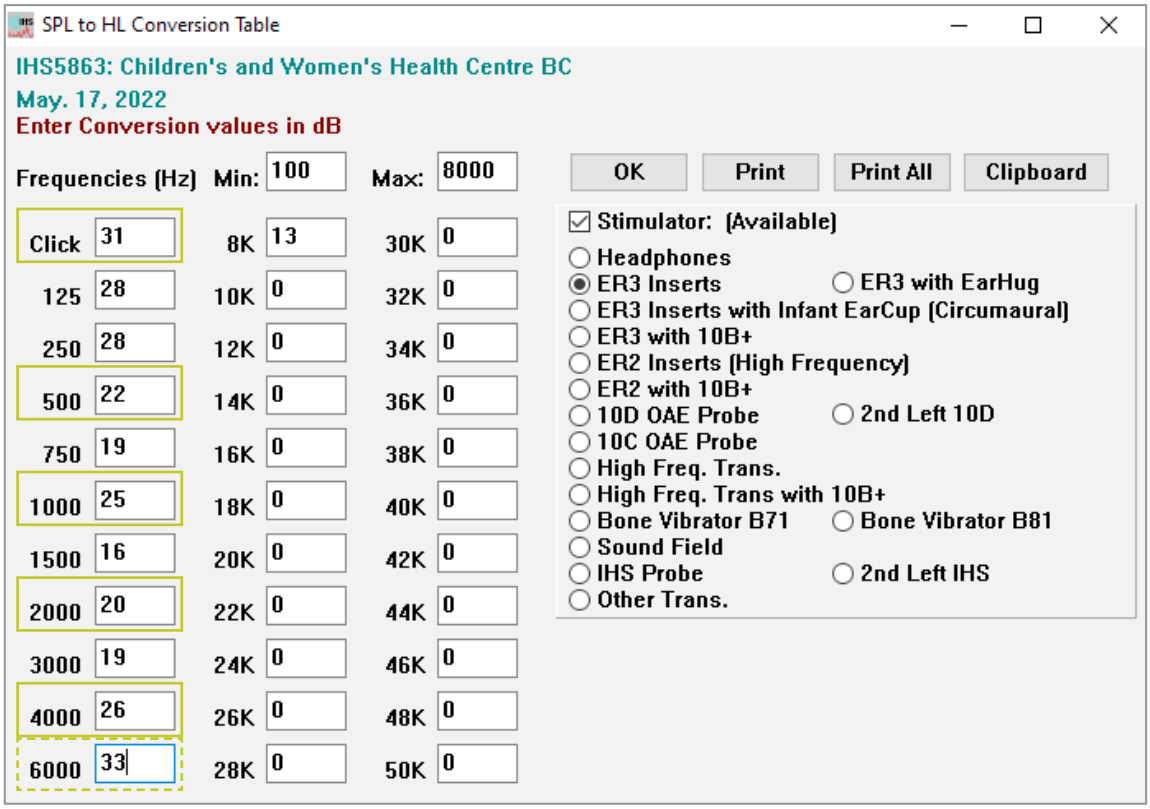


Figure 2: SmartEP "SPL to HL Conversion Table": BCEHP calibration offset targets for ER3-A insert earphones (Small & Stapells, 2017; Stapells, 2000). The 6000-Hz calibration offset (dashed box) has been estimated from the literature.

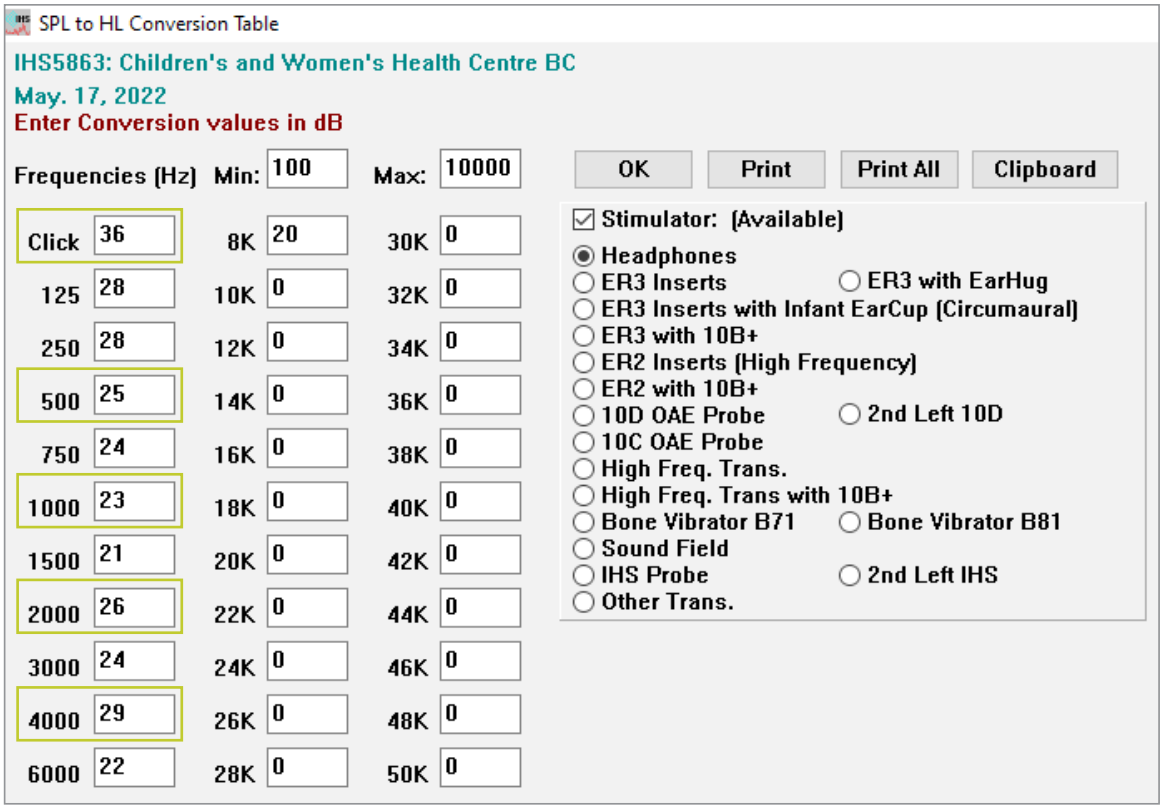


Figure 3: SmartEP "SPL to HL Conversion Table": BCEHP calibration offset targets for supra-aural headphones (Small & Stapells, 2017; Stapells, 2000).

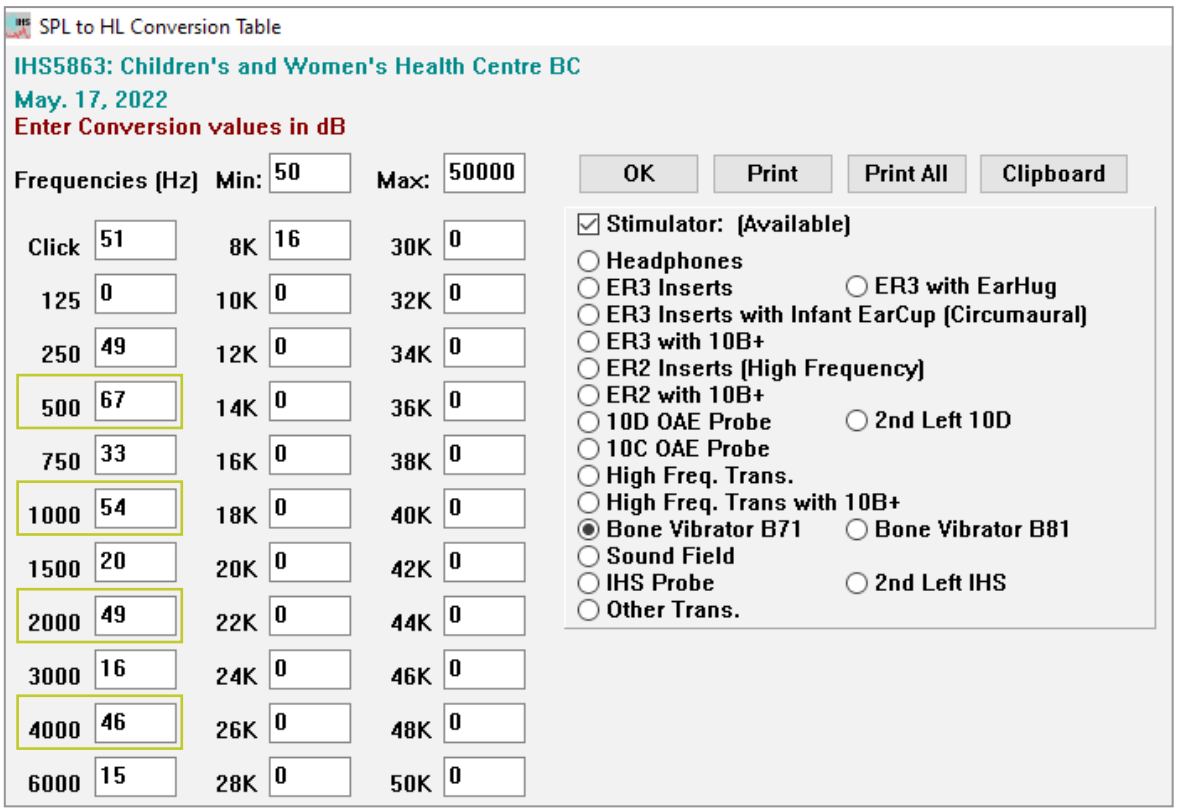


Figure 4: SmartEP "SPL to HL Conversion Table": BCEHP calibration offset targets for B-71 bone vibrator (Stapells, 2000; Small & Stapells, 2003, Hatton et al., 2012, BCEHP, 2012). The 4000-Hz offset is from the "both ears occluded" results of Small and Stapells (2003). Note that the "80 dB SPL" for BC stimuli actually represents BC stimuli calibrated at "80 dB re:1 µN".

PART 2: CALIBRATION INFORMATION SPECIFIC TO IHS SYSTEM

As noted above, the SmartEP system provides the option to calibrate: (i) in dB SPL or (ii) in dB HL (in this case, "HL" is actually "nHL"). The following provides instructions for both methods. *However, the "HL" method (where the "SPL to HL" offset is added) is the preferred method.*

(i) Changes to the calibration of the SmartEP system are made in the main IHS start-up menu in the "Launch Pad" under "System" then "Calibration". To access this area, enter user initials in the first box, then the usual password in the second box. The "IHS Calibration Module" window will pop up as shown in Figure 5A. **This is the only page that is modified during calibration and will typically only be adjusted by a calibration specialist!**

(ii) To calibrate the SmartEP system, first select the transducer that needs to be calibrated. To do so, go to "IHS Calibration Module" and select "Settings", then "Transducer:" as shown in Figure 5B. The output for each transducer (TDH/headphones, insert earphones/ER3, bone vibrator/B71/B81), stimulus (0.5-, 1-, 2-, 4-, & 6-kHz, Clicks) and channel (Chn1, Chn2) must be calibrated individually.

Calibration using "SPL" mode:

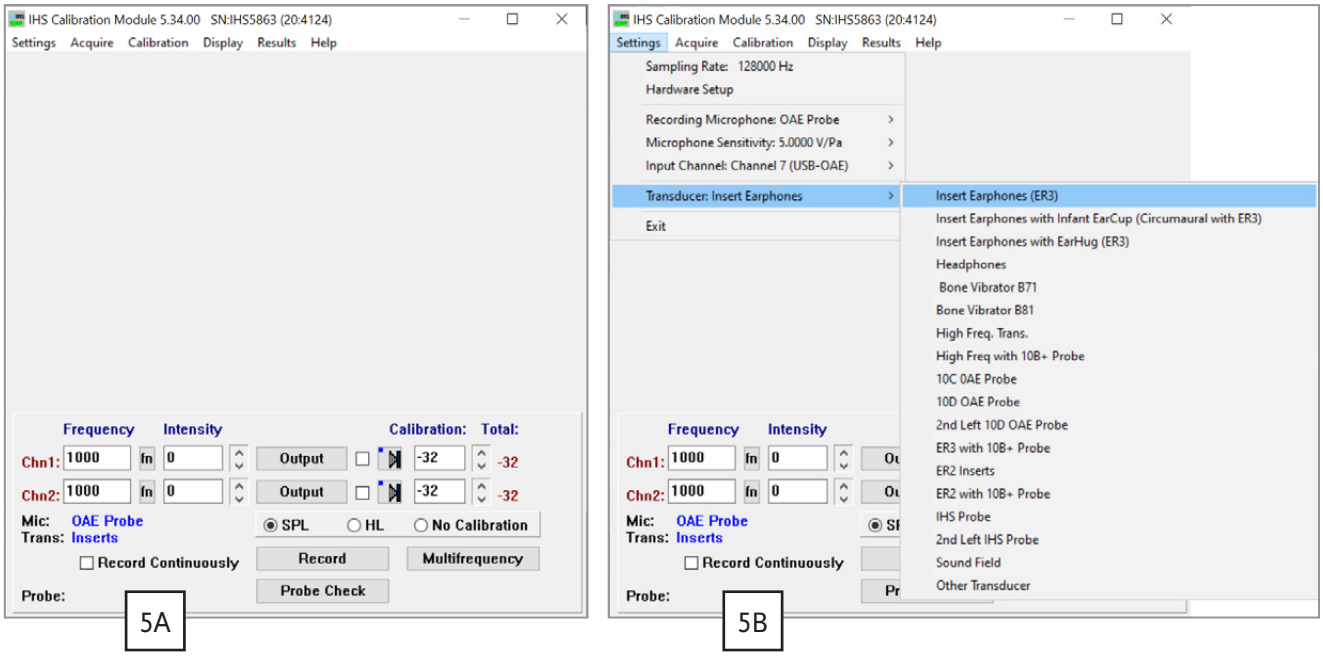


Figure 5A & 5B: (i) 5A: "IHS Calibration Module": changes are made in this section if the output of a specific transducer does not meet BCEHP targets. A target calibration output needs to be entered in the "Intensity" field (i.e., 80 or 90 "dB SPL" for AC stimuli AND 80 "dB SPL" for BC stimuli). To make a measurement, the box to the left of "Calibration:" is clicked and "Record" is selected; (ii) 5B: "IHS Calibration Module- Settings": transducer type is selected in this screen; the options for ABR audiometry are "Insert Earphones (ER3)", "Headphones" and "Bone Vibrator". To calibrate in "SPL" mode, "SPL" is selected.

"Calibration" offsets are adjusted up or down by the calibration specialist for each type of transducer (Figure 5A). These numbers are always negative. For example, if the calibration specialist is testing insert earphones/headphones and enters "80" in "Intensity" (dB SPL), clicks the boxes to the left of "Calibration", presses "Record" and measures the output on a sound level meter (SLM: RMS & linear), the output should read 80 dB SPL. If the output on the SLM is above or below 80 dB SPL, the calibration specialist adjusts the "-32 offset" accordingly until an 80 dB SPL output is measured on the SLM.

(**NOTE:** ANSI allows output levels to be within ±3 dB of the target; however, in practice, equipment calibration specialists adjust output levels to be within ±1 dB of the targeted output level.)

NOTE: *the IHS system automatically factors in the offsets provided by the* ***"SPL to HL Conversion Table" (BCEHP-specific calibration targets)*** *when calculating the "Total Calibration" for any given frequency using a specific transducer.* ***"Total Calibration"*** *is therefore the combined result of the changes made within the* ***"IHS Calibration Module" AND the offsets provided in the "SPL to HL Conversion Table". The values in the "SPL to HL Conversion Table" do not change.*** *If these offsets do not match those of Stapells (2000), Small and Stapells (2003), Hatton et al. (2012), BCEHP (2012), the dB nHL level of the stimuli generated will be incorrect.*

(iii) Changes made in the "IHS Calibration Module" automatically transfer to the "Sound Calibration Table" within the SmartEP module as shown in Figure 6B. For example, the -32 calibration factor indicated in Figure 5A for a 1 kHz tone presented via inserts should correspond to the same condition in the SmartEP Sound Calibration Table, as shown in Figure 6B.

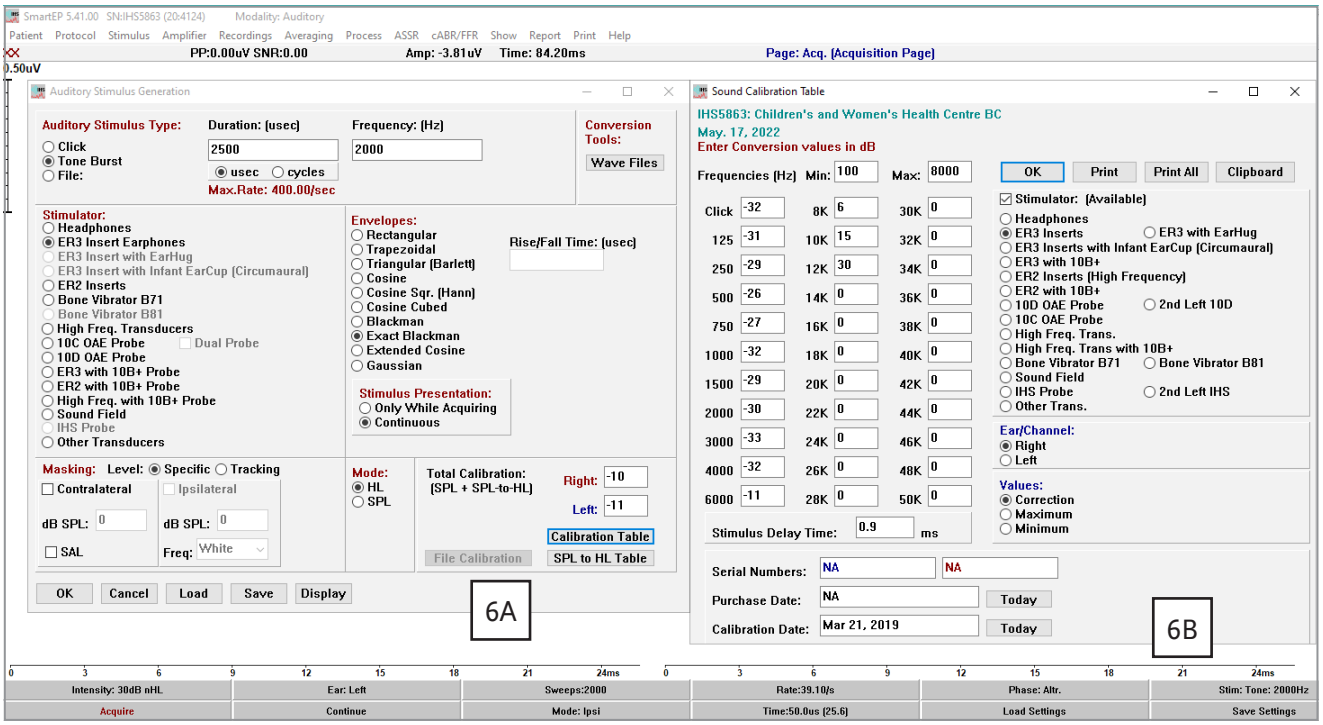


Figure 6: IHS windows that show calibration offsets for the "SmartEP": (6A) "Auditory Stimulus Generation" window and (6B) "Sound Calibration Table". The screen behind these tabs is the main SmartEP user window. The values in Figure 6B are adjusted by a calibration technician within the "Launch Pad" "I.H.S Calibration Module".

Calibration using "HL" mode:

Using this method, "HL" is selected, as shown below:

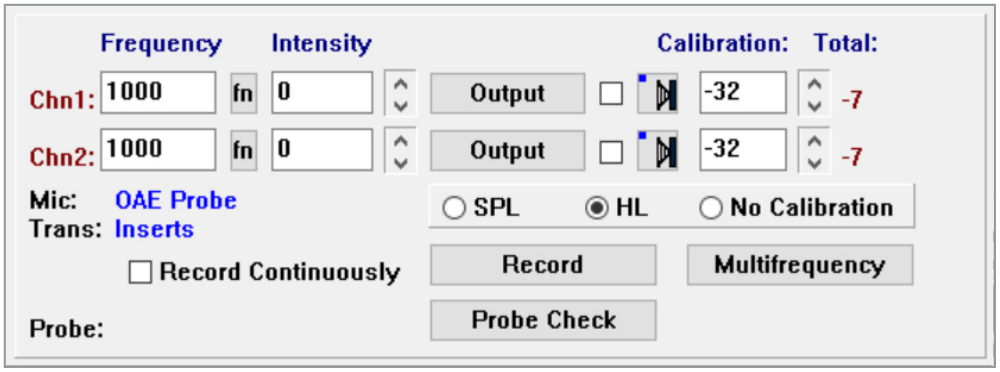


Figure 7: IHS window showing calibration window set to "HL" mode. In this mode, setting the "Intensity" to "80" will output a continuous tone at 80 dB plus the "SPL to HL" offset for the specified frequency. This is the preferred method for BCEHP calibration. Except for the targets, all other procedures are the same as with the "SPL" mode described above.

The BCEHP "I.H.S. SmartEP Calibration for ABR" form used for routine annual calibration record keeping, shown at the end of this appendix, requires use of the "HL" mode.

(iv) ***Another step that is recommended in the calibration process is to verify that the stimulus delivered by the transducer to the patient is correct (i.e., calibrate the short duration version of the stimuli).*** *To do so, go to "Launch Pad", open "SmartEP", and go to "Load Settings". Select each AC and BC stimulus for each transducer type and verify that what is delivered to the patient is the expected output. For calibrations conducted by* equipment calibration specialists, long-duration stimuli *generated in the "Launch Pad- IHS Calibration Module"* are used to measure the output for each stimulus. However, because the actual stimuli sent to patients are short in duration, *we need a different approach to verify that the stimuli are properly calibrated. The appropriate method for calibrating short-duration stimuli is explained below:*

For **AC brief tones**, measure the peak SPL using the SLM using a presentation level of 80 dB nHL. When the IHS stimulus level is set to 80 dB nHL, the "peak SPL" value measured on the SLM should be 3 dB greater than the dB peak-equivalent SPL (dB pe SPL) target for AC brief tones (80 dB dial + dB offset shown in the SmartEP "SPL to HL Conversion Table").

> Example 1: If the dial setting is **80 dB nHL** for a **2000-Hz AC brief tone** using an **ER3-A** transducer, the **target peak SPL** on the SLM should be: **103 dB peak SPL** = 80 dial + 20 dB offset (Figure 2) + 3 dB

For **AC clicks**, testing should be completed at 90 dB SPL and the "peak SPL" targets are provided rather than the dB pe SPL targets. Note that a 3-dB adjustment is not required for clicks because peak measurements do not overestimate the output for clicks due to the shape of the stimulus (i.e., rectangular onset/offset with brief flat plateau).

> Example 2: If the dial setting is **90 dB nHL** for an **AC click** using an **ER3-A** transducer, the **target peak SPL** on the SLM should be: **121 dB peak SPL** = 90 dial + 31 dB offset (Figure 2)

For **Bone-Conduction brief tones**, the target on the SLM depends on the characteristics of the individual artificial mastoid used to calibrate the stimuli. **We require the use of a B&K** *4930 artificial mastoid or equivalent as shown in Figure 8.*

Figure 8: Example of appropriate equipment need for electroacoustic calibration: B&K 4930 artificial mastoid and Larson Davis sound level meter set up for bone-conduction calibration.

NOTE: No substitute for the style of artificial mastoid shown in Figure 8 is allowed at this time. DO NOT USE the Larson Davis AMC493 artificial mastoid – shown in this box – that converts force output to acoustic signals. *This device has poor output stability—noted by UBC researchers and calibration specialists independently*[1].

[1] A newer version of the Larson Davis AMC493, the AMC493B, was recently introduced and has been reported to be more stable than the original AMC493; the use of this device is currently under review by BCEHP but has not yet been authorized for calibration use.

Electroacoustic calibration of BC stimuli requires a few extra steps compared to calibration of AC stimuli. This section will describe these extra steps in detail:

Each ***individual artificial mastoid*** has a ***unique "force sensitivity" and "frequency-specific corrections"*** that are applied to determine target dB re: 1 µN values for different stimuli. **[NOTE: all artificial-mastoid specific examples below are for equipment used by Prof. Susan Small at UBC]**

How to convert unique **"Force Sensitivity"** values in mV/N to V/N to dB (specifications come with artificial mastoid):

Example: B&K artificial mastoid

131 mV/N = .131 V/N

20log (.131) = **-17.65 dB**

NOTE: force sensitivity for one specific artificial mastoid (same across frequency)

One other important calibration factor to check: the SLM you use should deliver 120 dB SPL when 1.0 Volts is applied to it – this step essentially involves calibration of the SLM being used before conducting stimulus calibrations – actually applies to AC and BC calibrations. This step is not required for every calibration but should be done periodically to ensure accuracy:

1. If you use a Larson Davis SLM, go to the calibration screen, set "Calibration level" to 120 dB, then apply 1.0 Volts at 1 kHz using alligator clips attached to a microdot cable and the SLM (Figure 8).
   a. to apply a voltage to calibrate a SLM microphone, a CA22 AC 1.0 Volt generator can be used (any other accurate 1-volt input can also be used)
   b. select "Check" to determine SPL output then press "Change" in the calibration screen.
   c. use the offset for the 1-inch microphone the remainder of the time to calculate the target SLM level; microphone sensitivity should remain stable unless damaged

(**NOTE:** If the 1-inch microphone sensitivity is known, you can also go backwards and determine xx Pa/ V to determine if a correction is needed)

2. The next step is to use a sound generator with known output (e.g., 114 dB for sound generator commonly used with Larson Davis SLM) to calibrate the SLM when using a 1" mic (typical equipment for AC and BC transducer calibrations) – then apply the 1 Volt with the artificial mastoid in place

Example: if you obtain 121.8 dB SPL for the 1.0 Volt input, add 1.8 dB to the SLM target calculation below – this will always be the correction unless the SLM's calibration changes; can periodically assess this as described.

Now, with all calibrations of necessary equipment completed, we can calibrate IHS BC stimuli (short-duration stimuli that would be presented to a patient).

Example: To determine target SLM values for BC brief-tones for 0.5 and 2 kHz presented at **30 dB nHL**, you need to calculate the target SLM values in dB re:1 µN. The following examples illustrate how the target SLM values in dB re:1 µN are calculated:

0.5 kHz: **30** + 67* – 17.65** – 0.5*** + 1.8**** = 80.65 dB in dB re:1 µN
2 kHz: **30** + 49* – 17.65** + 2 *** + 1.8**** = 65.15 dB in dB re:1 µN

*BCEHP frequency-specific *calibration offset targets for B-71 bone vibrator*

** #1 Force sensitivity for specific artificial mastoid (same across frequency)

*** Correction values for specific frequencies are derived from a graph that comes with each individual artificial mastoid: "frequency specific response at constant dynamic force" (frequency specific)

**** SLM offset if any—derived from procedures for calibrating SLMs above

NOTE:* Calibration must be conducted using the targets indicated on the "BCEHP calibration offset targets"; targets also shown on the "BCEHP SmartEP Calibration for ABR" form AND must be recorded for each BCEHP ABR device.

PART 3: VERIFICATION OF INTEGRITY OF STIMULUS

Calibration of the stimulus level is essential, but it is also important to ***check that all stimulus characteristics*** meet the standard for ABR testing. There are different types of equipment that can be used for this purpose. For example, if an oscilloscope is available, it is very helpful to visually inspect the stimuli used to elicit click and brief-tone ABRs. The tolerances for each measure are stipulated in the standard used for calibration (e.g., ANSI).

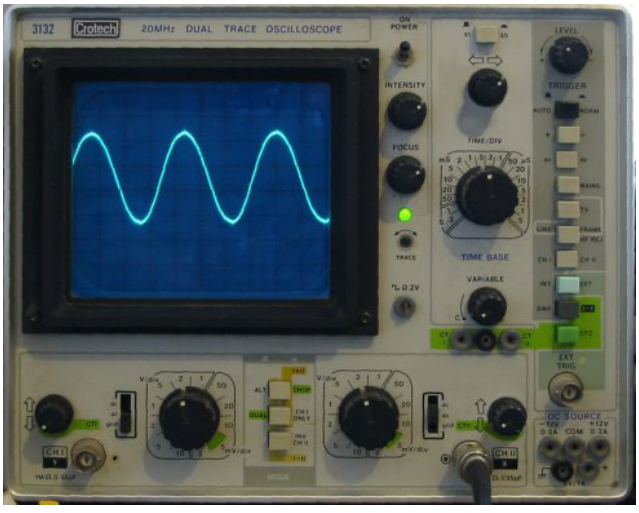


Figure 9: Oscilloscope showing a pure tone.

Oscilloscopes (or, alternatively, laptops with appropriate software) are very helpful for checking different characteristics of a stimulus, but other equipment can also be used to verify different aspects of stimulus accuracy.

(**NOTE:** equipment used by calibration specialist to make these checks, when needed, will vary.)

Some examples:

- ***frequency:*** with oscilloscope, can verify the cycle per second of a stimulus (can also use frequency counter, as is often done by equipment calibration specialists)
- ***polarity:*** with oscilloscope, can verify rarefaction and condensation stimulus polarities
- ***asymmetry***: with oscilloscope, degree of click asymmetry can also be visualized
- ***ringing***: this often occurs when transducers get worn out after years of use, in particular when high stimulus levels are used over a period of time; on the oscilloscope, extra stimulus oscillations will be seen that were not present when the transducer was new and working fully to specifications
- ***clipping:*** a clipped waveform occurs when an amplifier produces more power than it was designed to produce; in the frequency domain, clipping produces strong harmonics in the high frequency range; clipping can damage the transducer

> ***NOTE: Typically, calibration technicians will check on all aspects of the integrity of the stimuli used for ABR testing at the annually scheduled calibration visit UNLESS problems are noted and troubleshooting is needed sooner.***

BC Early Hearing Program

A service of BC Children's Hospital
and the Provincial Health Services Authority

I.H.S. SMARTEP (ABR) CALIBRATION

Date (Year/Mo/Day): _____

Owner: BCEHP _____ **I.H.S. S/N:** _____ **Software version:** _____

ABR Site: _____ **Technician:** _____

*Transducer: TDH 49 (use NBS-9A/AEC100 coupler or equivalent)						ALL MEASURES IN IHS "NHL" MODE+	
AC Stimuli	**SPL to HL Offsets#** re: Small & Stapells, 2017	**I.H.S. dB Calibration Offset**		**Attenuator Setting ("Dial") in dB HL**	**Target dB SPL @ 70 dB nHL**	**dB SPL Reading on SLM (Phones); must be within 1 dB of target**	
		Left	**Right**			**Left**	**Right**
500 Hz	25pe			70	95		
1000 Hz	23pe			70	93		
2000 Hz	26pe			70	96		
4000 Hz	29pe			70	99		
6000 Hz	N/A			70	N/A		
Click	**36peak**			**70**	**106p**		

*Transducer: ER3-A (use 2-cc DB0138 coupler HA-2 or equivalent)						ALL MEASURES IN IHS "NHL" MODE+	
AC Stimuli	**SPL to HL Offsets#** re: Small & Stapells, 2017	**I.H.S. dB Calibration Offset**		**Attenuator Setting ("Dial") in dB HL**	**Target dB SPL @ 70 dB nHL**	**dB SPL Reading on SLM (Inserts); must be within 1 dB of target**	
		Left	**Right**			**Left**	**Right**
500 Hz	22pe			70	92		
1000 Hz	25pe			70	95		
2000 Hz	20pe			70	90		
4000 Hz	26pe			70	96		
6000 Hz	33pe			70	103		
Click	**31peak**			**70**	**101p**		

*Transducer: B71/B81 (Bone) (use B&K 4930 Artificial Mastoid (AM))						ALL MEASURES IN IHS "NHL" MODE+
BC Stimuli	**FL (dB re: 1µN) to HL Offsets#** re: Small & Stapells, 2017	**I.H.S. dB Calibration Offset**	**Attenuator Setting ("Dial") in dB HL**	****Artificial Mastoid dB re: 1 µN SLM correction**	**Target dB re: 1 µN @ 30 dB nHL**	**dB re: 1 µN on SLM (Bone); must be within 1 dB of target**
500 Hz	67pe		30			
1000 Hz	54pe		30			
2000 Hz	49pe		30			
4000 Hz	46pe		30			
Clicks	**51peak**		**30**			

These are actually SPL- (or FL-) to-nHL offsets but we are using "I.H.S." terminology to be clear.

* Offsets above *require* use of NBS9A (TDH) or DB0138 HA-2 (ER3A) couplers with 1-inch microphone, or B&K 4930 artificial mastoid.

** Each individual B&K 4930 has force sensitivity and frequency-specific corrections that are applied to determine target dB re: 1 µN. **NOTE:** DO NOT USE Larson Davis AMC493 artificial mastoid – has poor output stability.

\+ In "NHL mode" (termed "HL" by I.H.S.), the I.H.S. adds the offsets and outputs a long-duration tone. Output measures are thus in dB SPL.

Comments:

SLM S/N: _____

TDH 49 S/N (L): _____ **S/N (R):** _____

ER3A S/N (L): _____ **S/N (R):** _____

B71/B81 S/N: _____ **Artificial Mastoid S/N:** _____

Company Name & Contact:

APPENDIX ABR5 – BONE-CONDUCTION HAND-HELD TRANSDUCER INSTRUCTIONS

Responsibility for appropriate application of the BC transducer lies with the testing ABR Audiologist. If BC-ABR results are abnormal, the audiologist must ensure it is not due to BC incorrect technique.

BCEHP recommends that the transducer be held by the ABR Audiologist or a trained assistant. When unavoidable, a family member may hold the transducer after instruction.

POSITION

The transducer should be applied to the upper mastoid area/temporal bone superior to the meatal opening. It should not come into direct contact with any electrode or electrode lead. Electrode leads should be directed away from the transducer and its supply leads, to the extent possible.

HOLDING

The transducer should be applied to the baby's head with the thumb and middle finger holding the supply lead at the point of attachment and the index finger applying force towards the head on the rear surface of the transducer. It should not be held by its sides.

FORCE

The application force should be approximately 400g (about 14 oz, or 1 lb). The force should be firm and steady but not excessive. Opposing force on the other side of the head may be required.

TRIAL

Before testing, the family member should demonstrate the holding technique and application force on the ABR Audiologist's hand.

ALERTING

The family member should be encouraged to alert the ABR Audiologist if for any reason the required positioning and force are not maintained during an ABR measurement.

APPENDIX ABR6 – WAVE I-V INTERPEAK INTERVAL NORMATIVE DATA

"Maximum I-V (3SD)" represents the maximum I-V for normal. ***Values greater than this are considered abnormal/prolonged.***

Age group: if infant's age not represented, use closest age group *above* infant's age. If I-V is normal for that age group, then the I-V is clearly normal for that infant.

ABR I-V NORMS			
Corrected AGE (mos)			**MAXIMUM I-V (ms)** (mean+3SD)
	-1.25		7.54
	-0.5		6.84
	0.5		6.80
	1.25		6.25
*	2		6.10
*	3		5.91
	3.75		5.77
*	6		5.55
	7		5.46
*	9		5.41
	10.25		5.38
*	12		5.34
*	16		5.26
	26.5		5.04
	39.5		5.00
	52.5		4.94
	65.5		4.72
	ADULT		4.96

*= from linear interpolation (between adjacent ages)

Normative data adapted from Eggermont & Salamy, 1988. Values are adjusted to BCEHP's use of 80 dB nHL and 19.1/s rate.

APPENDIX ABR7 – ABR TROUBLESHOOTING NOISE

WHAT ARE THE FIRST STEPS IF/WHEN I SEE NOISE IN A RECORDING?

- Determine if the noise is stimulus locked or is random. A noisy baby or electrically noisy room typically is random noise, which reduces with averaging but could require too much averaging time to reach an acceptably low level.
- Stimulus-locked issues do not reduce with averaging.
- Determine whether the stimulus-locked issue is physiologic or non-physiologic.

HOW IS PHYSIOLOGIC NOISE DIFFERENTIATED FROM NON-PHYSIOLOGIC NOISE?

- Artifact is physiologic if it goes away with a clamped-tube condition (unless it is general noisiness of the baby).
- Artifact is non-physiologic if it remains with the clamped-tube run.

HOW DO I REMEDY PHYSIOLOGIC NOISE?

- If it is random (i.e., non-stimulus-locked) physiologic noise, then either try to get the baby in a quieter state (e.g., more comfortable, reposition baby for more neck relaxation) or defer testing until baby is in deeper sleep.
- If there are stimulus-locked responses (e.g., PAMR or steady-state responses), these can make identification of specific waveforms difficult. A stimulus-locked waveform that is proven to be physiologic (i.e., goes away with the clamp tube run), indicates the auditory system has responded to the stimulus. However, these can be problematic if you need to do accurate measures of wave V latency and amplitude such as for ipsi/contra asymmetries or ANSD analyses.
- There are several remedies that could help with PAMR including (i) ensuring the "negative" electrode is placed low on the mastoid; (ii) ensuring the baby is in a quiet sleep; (iii) ensuring the baby in a position that does not create any tension in the neck; (iv) rarely, slow the rate down (this should be done only if wave V clarity is essential).
- Steady-state responses are not typically a problem for ABR testing in infants.

HOW DO I REMEDY STIMULUS-LOCKED, NON-PHYSIOLOGIC ELECTRICAL INTERFERENCE?

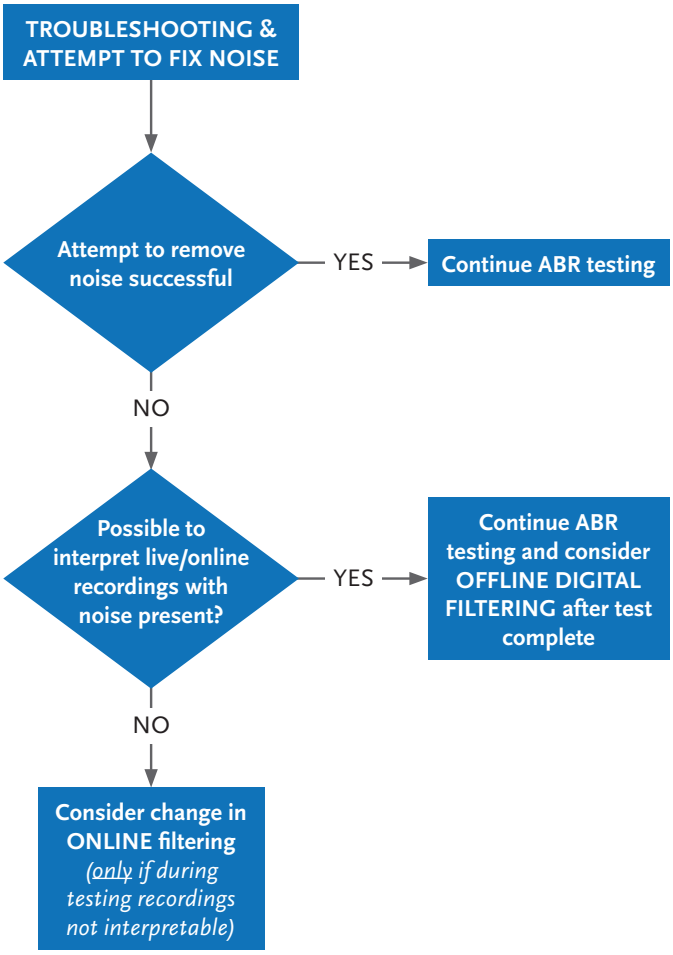
- Turn off all possible sources of electrical interference (e.g., lights, fans, printers, cell phones).
- Unplug anything plugged in, including extension cords and power bars.
- Ensure that the electrode leads and transducer wires (insert earphones/supra aural headphones/bone oscillator) are not overlapping.
- Ensure electrodes are braided/taped together.
- Stretch out all cables/wires, as coiled wires act more like an antenna.
- Ensure that all cable connections are secure.
- Check that electrodes are all secured (i.e., not lifting off).
- Ensure electrode impedance is as low as possible and the same on all channels.

- Reposition the baby and equipment so that the baby is as far away from the computer and other sources of electrical artifact as possible. Each clinic will need to determine which areas in their clinic work best for them.
- Move amplifier box to see if another position might be better (sometimes small moves can make a big difference).
- Change the stimulus rate slightly (e.g., 39.1/s to 38.9/s). The point of making small rate changes is to unlock the averaging process from the non-physiologic noise.
- In the NICU or operating room ask that equipment be battery powered, where possible, or turned off if it's not necessary.
- Sometimes electrical interference will be transient and will go away on its own.
- The above strategies are preferred to the filtering strategies noted below and should be attempted first.

WHAT CAN I TRY WHEN THE PATIENT IS NOT PRESENT IF I SUSPECT NON-PHYSIOLOGIC ELECTRICAL INTERFERENCE?

- Turn on amplifier (USB box) without electrodes or Y-cord, and begin collecting. You should get RN of around 0.04 µV. If the RN is large, this is an indication of internal (IHS) noise.
- Short the + and – together for one channel (using the y-cord), and collect data from that channel. You should get a low RN value (0.08 µV or less).
- Plug in all cords as you would for a 2-channel recording, place the recording end of the electrodes in the location of interest (e.g. where baby's head will likely be in a real testing situation) and begin collecting. This will give you an indication of noise for that given location (assuming no internal IHS noise issues). You should find that the EEG is noisier when closer to sources of interference such as lights and computers. You should also be able to find areas of less EEG noise as well, which should be better for testing.
- Attach electrodes in normal array for 2-channel recording to a volunteer. Attach headphones; collect with your subject as relaxed as possible (neck supported, as close to asleep as possible) using a stimulus at 40 to 50 dB nHL. You should be able to see a response (ensure you are using a normal-hearing subject) as well as obtain low RN values.

WHAT ALTERNATIVES ARE THERE FOR NON-PHYSIOLOGIC ELECTRICAL INTERFERENCE WHEN THE ABOVE STRATEGIES HAVE FAILED TO REMOVE OR REDUCE THE NOISE? SEE FLOWCHART.



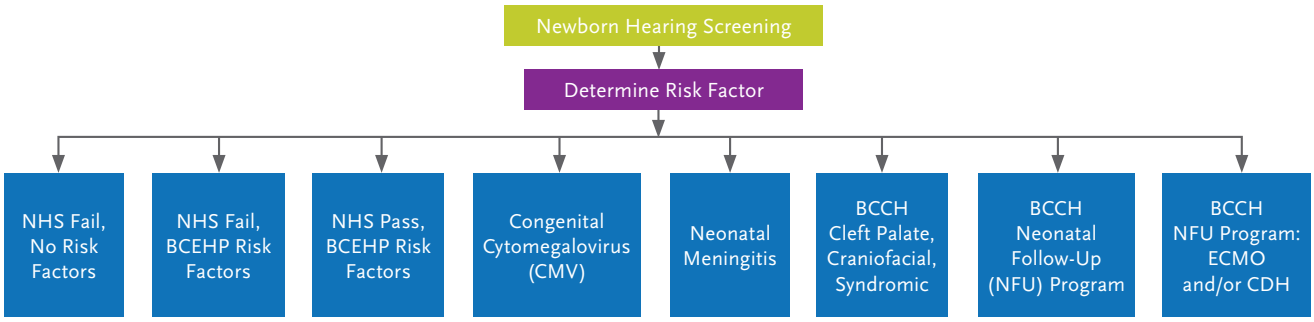
APPENDIX ABR8 – AUDIOLOGIC MONITORING AND CARE PATHS

For Audiologic Monitoring and Care Paths, see BCCH Audiology website.

BCEHP and BCCH, in collaboration with Public Health Audiology (PHA), have jointly created a series of flow diagrams called "Care Paths" that outline recommendations regarding timing of testing and frequency of audiologic monitoring for children with specific risk factors. **These Care Paths are minimal practice guidelines; additional assessment may be indicated on a case-by-case basis and is determined by the audiologist/PHA clinic following the child. As a general principle, children who fall under more than one Care Path should be followed based on the most conservative follow-up schedule.**

Note that it is the responsibility of the hearing screener to make the initial audiology referral when the risk factor(s) is known at the time of hearing screening. It is the responsibility of the audiologist to make all subsequent audiological referrals.

Consultation with a BCEHP PSA/BCCH team audiologist is recommended if hearing status remains inconclusive after two appointments due to audiologic complexity. This consultation may result in referral to BCCH and/or consideration of sedated ABR. A summary of the available Care Paths is provided below.



BCEHP NHS REFERRAL FOR AUDIOLOGICAL SERVICES

All infants who fail NHS should be referred for ABR audiometry between 4-8 weeks corrected age, as indicated in the "NHS Fail, No Risk Factors" and "NHS Fail, BCEHP Risk Factors" Care Paths.

Infants who pass NHS or who have normal hearing at the time of their initial ABR audiometry appointment but are identified with one or more risk factor(s) for hearing loss will be referred for audiological monitoring depending on their risk factor(s). If multiple risk factors are present, the most conservative follow-up schedule applies.

Basic audiological monitoring: these infants pass NHS but have conditions at birth that have been identified by BCEHP as being associated with hearing loss. They should be seen for behavioural audiometry at 9 months and 3 years corrected age at their local PHA clinic, as outlined in the "NHS Pass, BCEHP Risk Factors" Care Path.

See Section 3.3 in the BCEHP Hearing Screening Protocol for a detailed list of BCEHP risk factors.

SPECIALIZED AUDIOLOGICAL MONITORING

The CONGENITAL Cytomegalovirus Care Path summarizes monitoring recommendations for children with congenital CMV. All children confirmed as having congenital CMV must be followed closely. In British Columbia, children with suspected or confirmed congenital CMV (cCMV) infection are typically seen for initial ABR at 4-8 weeks corrected age, regardless of screening outcome. *Upon physician referral only, initial ABR may be completed within the first 3 weeks of life (but not prior to 37 weeks gestational age), to help inform*

decisions about antiviral treatment. Children with cCMV have a high probability of both congenital and late-onset PHL, as well as frequent comorbidities that may complicate or prevent later behavioural testing. Long-term monitoring beyond the initial ABR is required because of the lengthy time course over which delayed expression of PHL may occur following cCMV infection.

The Meningitis Care Path and Clinical Practice Guideline summarizes monitoring recommendations for children identified with meningitis, irrespective of pathogen. These children will be seen for initial ABR audiometry as soon as medically possible following recovery from the acute phase of the illness, regardless of screening pass or fail, but not prior to 44 weeks corrected age.

Factors to consider with meningitis include the time of onset of PHL and its progression. In bacterial meningitis, there is also risk of ossification of the cochlea that may compromise cochlear implantation. Detection of any sensorineural abnormality indicates urgent referral to an Otolaryngologist and the BCCH Cochlear Implant program. If a treating physician sees fit to refer the baby for ABR assessment on the basis of presumptive meningitis, the baby is at risk due to the physician determination itself, and the ABR should be treated as though the meningitis was confirmed.

The Auditory Neuropathy Spectrum Disorder Care Path summarizes the monitoring schedules for children identified as having this disorder. ANSD does not affect all children in the same way, and its effects range from mild to severe. ANSD differs from other types of hearing loss in that a child's hearing levels and speech understanding abilities cannot be predicted from infant hearing tests. A BCEHP brochure and video explaining the basics of ANSD in lay language for caregivers is available.

SPECIALIZED BCCH TEAMS

The **BCCH Neonatal Follow-Up (NFU) Program** is a multidisciplinary team program that enrols families to participate in regular interdisciplinary team review and assessment. Enrolment is offered to families whose infants have certain perinatal/risk factors that place them at high risk of additional/complex needs or for whom little is known about potential outcomes. Patient recruitment criteria are available on their website.

The BCCH NFU Care Path outlines the typical schedule for children followed by this program for which hearing assessment is recommended. The team intake review conducted by the BCCH NFU program is completed two months prior to each team visit and each discipline reports on whether their assessment is needed for that particular child. Children are most typically seen by audiology though the NFU program at 8 months and 3 years corrected age.

Children with **Congenital Diaphragmatic Hernia (CDH) or those that have received Extracorporeal membrane oxygenation (ECMO)** are also followed by the BCCH NFU team. The BCCH NFU CDH/ECMO Care Path **summarizes recommendations for children with CDH/ECMO**. Regardless of hearing screening result (pass or fail), these children will be offered initial ABR testing at 4-8 weeks corrected age. Children with the CDH/ECMO risk factor(s) will be closely monitored up to age 4.5 years, both at their local PHA clinic and at BCCH.

The BCCH Cleft Palate/Craniofacial Team is a multidisciplinary team program that follows children with cleft palate and other craniofacial differences. More information about the program is available on their website. A series of Care Paths have been developed for this program. Families from Vancouver Island and Kelowna that are followed by their local Cleft Palate Program may follow these guidelines should they choose, but specific protocols for each centre may also be in place, which are beyond the purview of this protocol.

Note that monitoring schedules for the BCCH Neonatal Follow-Up Program and Cleft Palate/Craniofacial teams are maintained by their respective team audiologist.